

**Health care innovations from policy to practice:  
A case study of a rapid HIV testing trial in  
general practice**

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**A thesis submitted toward the degree of Doctor of Philosophy**

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I, Heather Claire McMullen confirm that the research included within this thesis is my own work or that where it has been carried out in collaboration with, or supported by others, that this is duly acknowledged below and my contribution indicated. Previously published material is also acknowledged below.

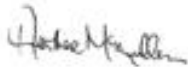
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**McMullen, H**, Griffiths, C, Leber, T, Greenhalgh. Explaining high and low performers in complex intervention trials: a new model based on diffusion of innovations theory. *Trials*. 2015; 16: 242

This published paper emerged from my independent PhD work. The details of the collaboration are clearly articulated in Part 2 of the thesis. My two PhD supervisors and one RHIVA2 trial team member are co-authors.

Leber, W, **McMullen, H**, Anderson, J et al. Promotion of rapid testing for HIV in primary care (RHIVA2): a cluster randomised controlled trial. *Lancet HIV*.2015; (published online April 29) doi: S2352-3018/S2352-3018(15)00059-4.

My PhD work is nested in the larger RHIVA2 trial of rapid HIV testing in primary care for which I acted as the trial manager. The final trial paper has been published with the trial team as authors, including myself. This work presents the context for my PhD work though the work presented in the thesis was independent from the trial in all other respects.

I discussed the work on 'equivocation' and the pragmatic trial featured in Chapter 12 with Dr. Megan Clinch. An abstract was produced by the two of us but was not formally published.

## **Acknowledgements**

Firstly, I would like to thank the research participants: the patients, providers and policy makers for their openness and participation in this study. Thank you to the National Institute of Health Research Doctoral training programme for funding my PhD and supporting junior researchers.

Thank you to my first supervisor, Trisha Greenhalgh for needed guidance, support and patience throughout the PhD from conception to completion, and for emphasising the importance of trying to make both theoretical and applied contributions. Being asked to push further and better articulate my work provided important lessons for which I am grateful. Thank you to my second supervisor, Chris Griffiths, who worked with me on RHIVA2, encouraged me to undertake a PhD and has provided support and supervision. My reviewers Sara Shaw and Stephanie Taylor provided helpful suggestions and guidance.

I am grateful to my colleagues at Queen Mary University of London: Megan Clinch, Deborah Swinglehurst and Anna Dowrick. Megan reignited my interest in academia at an important waning moment, helping me to see the study in a new light through the introduction to insightful literature. Deborah provided thoughtful feedback on parts of my work and reassurance about the academic journey. Anna has been a PhD comrade, interlocutor and friend.

My RHIVA2 colleagues, Jane Anderson, Danna Millet, Sifiso Mguni, Jose Figueroa and Werner Leber, worked with me on the trial and supported my decision to undertake a PhD. Jane additionally acted as an experienced guide to the world of specialised HIV care and helped me enter important spaces to undertake and present my work.

Thank you to my parents Alison and Rick for love, unconditional support and restful spaces and to Kyle and Nikki for being in my corner. Ailin Conant and João Paulo Marra Denófrío acted as edifying and inspiring presences in my life at key moments.

This work is dedicated to my Grandfather Alastair Middleton, who would have read the whole thing, and to my Uncle Ian Middleton who I wish could have completed his own exciting projects and benefited from some of what is described in this thesis.

## Abstract

The *UK National Guidelines on HIV Testing 2008* recommended that adults in areas where more than 2/1000 people were living with HIV be considered for an HIV test at the point of registration with general practice. The RHIVA2 trial of rapid HIV testing in primary care implemented and evaluated this recommendation across 20 general practices in a single UK borough using a pragmatic cluster randomised controlled trial (RCT) design. This trial, and the policy that underpinned it, reflected two more general developments: first, the move towards population screening to detect and treat disease in early and latent stages and second, the emergence of ‘pragmatic’ clinical trials that seek to account for complexity and measure interventions in their context of use.

This interdisciplinary case study uses multiple methods and theoretical frames to explore what happened in the RHIVA2 trial at both an empirical and a theoretical level. Sub-studies reveal how the trial was justified, enacted and became meaningful as a policy, as a trial, and as an intervention in the lives of patients. My analyses show that two operating logics informed the justification and enactment of the trial and patterned patient and provider experiences. The first, *the logic of normalisation for HIV* aims to treat HIV infection as a medical condition ‘like any other’. This logic emphasises general practice as a site of increased value and position in HIV management and as a space where population screening can be undertaken. Second, *the logic of the pragmatic trial* aims to measure interventions in the ‘real world’ but is revealed to produce unintended effects, raising questions about the claims of such trials to generalisability and reproducibility.

This thesis demonstrates how contrasting versions of the research event (‘multiplicity’) can be produced through different modes of inquiry, raising questions about the tension between situated and generalisable findings.



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## Glossary of terms:

A&E	Accident and Emergency
AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
ANT	Actor network theory
BASHH	British Association for Sexual Health and HIV
BHIVA	British HIV Association
BIS	British Infection Society
CD4	A measure of CD4 T lymphocytes (CD4 cells) in human blood
CDC	Centre for Disease Control
CLIA	Clinical Laboratory Improvement Amendments
CONSORT	Consolidated Standards for Reporting Trials
DoH	Department of Health
DOI	Diffusion of innovations
EMIS	Egton Medical Information Systems
GP	General Practice
GUM Clinics	Genito-Urinary Medicine Clinics
HAART	Highly active antiretroviral therapy
HCA	Health care assistant
HIV	Human immunodeficiency virus
HPA	Health protection agency
INSTI	Single use rapid assay for the detection of antibodies to HIV Types 1 and 2
ISRCTN	International Standard Randomised Controlled Trial Number
MRC	Medical Research Council
MSM	Men who have sex with men
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute of Health Research
NPHC	New Patient Health Check
PCT	Primary Care Trust
PHE	Public Health England
PRECIS	Pragmatic-explanatory continuum indicator summary
QMUL	Queen Mary University of London
RCT	Randomised Controlled Trial
RHIVA1	Rapid Human Immunodeficiency Rapid Assessment feasibility and acceptability study
RHIVA2	Rapid Human Immunodeficiency Rapid Assessment cluster randomised controlled trial in primary care
STS	Science and technology studies
UK	United Kingdom
WHO	World Health Organisation

## Chapter 1: INTRODUCTION

*'To explain how the world works is not to explain it away but to make new connections between social 'facts' that may provide unprecedented insight into the working of social worlds in general. One such insight concerns the excess of social experience - the historical surplus - at any point in time, that is experience which is not captured by current categories, and which points to alternative ways of seeing things and acting upon them - and hence to possible sites of social resistance or creativity; as the case may be.'* (Hastrup, 2004: p.466)

*'While good arguments are unambiguous, good stories leave room for a variety of interpretations. While sound arguments should be clear and transparent, powerful stories work by evoking people's imagination, empathy and irritation. While conflicting arguments work against each other, conflicting stories tend to enrich each other. And while adding up arguments leads to a conclusion, adding on stories is more likely to be a way of raising ever more questions. How might what went wrong here be prevented elsewhere? How could we transport what was successful here to other sites and situations? And if there is nothing to be done, if nothing is likely to lead to any improvement, then stories may be a source of consolation.'* (Mol, 2008: p.76)

This thesis tells two stories. One is about human immunodeficiency virus (HIV) and how new approaches to testing for HIV in the United Kingdom (UK) impact general practice organisations, health care providers and patients. The other is about how innovations such as HIV testing are evaluated in their context of use, using the experimental design of the randomised controlled trial (RCT). These two stories were brought together in a study of HIV testing in general practice where the innovation of point-of-care rapid HIV testing for newly registering patients in general practice was implemented and evaluated using a pragmatic RCT design. I was a member of the study team, acting first as a research assistant and then as the manager of the trial. This work left me with a number of questions about trial designs, HIV and innovations in health care. These questions, often surfacing as tensions, confusion or doubt, inspired the work presented here.

My initial research question was about variation in the uptake of HIV testing amongst general practices participating in the research trial in which this work is nested. Here, general practices were expected to implement opt-out rapid HIV tests to newly registering patients. Intervention practices showed wide variation in achieving this goal and I aimed to learn why some practices were better able to implement HIV testing than others. I hoped to explore, and to some degree explain, the variation in the uptake of rapid HIV testing in general practice. Over time, as I worked through this question it became apparent that a greater consideration of the policy context and the research design was required to account for my findings and provide explanations for the confusion and questions they were surfacing. My research questions began to transform and I started to ask what could be learned about the implementation and evaluation of a service innovation, such as the rapid HIV test, *as part of a pragmatic trial specifically?* In thinking through these questions and in recognition of the breadth of methods and data sources this would require, I recognised the need for a structure upon which to hang my work. It was then that I began to construct the two stories that are woven through the work presented in the thesis.

### **1.1 Story 1: Implementing a ‘normalised HIV’ through a population screening approach in general practice: the logic of normalisation for HIV**

The first story concerns population screening for HIV with emphasis on how such approaches inform transitions in what it means to be a ‘diseased’ body. Changes in the biomedical landscape of HIV mean that patients may live healthily with an HIV infection with little risk of passing the virus to others if they adhere to drug therapies. When such conditions are met, HIV can shift from a deadly acute infection to a chronic, manageable condition. As a result, there has been a large-scale push by the biomedical and HIV policy community to ‘normalise’ HIV testing and, to some extent, HIV infection, with an emphasis on the early detection of the disease. The logic of normalisation for HIV refers to a coherence of ideas, practices, approaches and ways of speaking and engaging with HIV where HIV infection is promoted as chronic, treatable, potentially non-infectious and considered as ‘any other medical condition’ with the right medical intervention. Within this logic, the altered potential of what it means biomedically to live with HIV is meant to and hoped to produce an improved social reality for HIV-positive individuals. I argue that the featured trial aims to implement this ‘new HIV’ - an early-detected, normalised, physically bearable and



potentially non-infectious HIV - through enacting many of the discursive practices enabled by a logic of normalisation surrounding HIV infection in the UK at the time of the trial.

## **1.2 Story 2: Evaluating ‘the scientific and the social’: The logic of the pragmatic clinical trial**

Story 2 is about the conduct of a pragmatic randomised controlled trial (RCT). The pragmatic trial research design is an explicit attempt to account for context while maintaining an RCT logic. It aims to overcome some of the limits of the traditional RCT by also accounting for ‘external’ factors and integrating the experimental design into the ‘real world’ of everyday clinical practice. Such trial designs are seen by the biomedical and health policy community as key to measuring complex interventions and in helping orient decisions in population health by providing evidence that aims to account for contextual factors (the ‘social’) while still providing a standard of evidence desired by biomedical paradigms (the ‘scientific’) (Kelly, 2008). Pragmatic trials are one response to the broader calls within health research to consider context and complexity and to better address the effectiveness of interventions in practical settings. The findings of such trials are also meant to be relatively generalisable to other similar settings. I argue that in RHIVA2 the pragmatic trial design was more productive as an experimental device than the current methodological approach recognised, potentially occluding some of what enabled the trial results.

## **1.3 A tale of two logics: The RHIVA2 Trial**

The RHIVA (Rapid Human Immunodeficiency Virus Assessment) 2 trial, the study in which this work is nested, simultaneously implemented and evaluated national guidelines on HIV testing. It brings together the story of population screening for HIV and the logic of normalisation, and the story of the logic of the pragmatic trial. By offering HIV testing to newly registered patients in general practice in a London borough where HIV is highly endemic, a recommendation from the *UK National Guidelines for HIV Testing 2008* [henceforth referred to as: 2008 National Guidance] was being implemented. As this was a new method of HIV testing for which UK RCT evidence did not exist, the RHIVA2 trial also evaluated this mode of testing using a ‘gold standard’ pragmatic RCT design. The trial aimed

to determine whether offering HIV testing to new patients, in the context of a new patient health check, would lead to the earlier diagnosis of HIV and at a greater rate of detection, which were public health priorities at the time (BHIVA et al., 2008). Offering testing in this way, informed by a logic of normalisation for HIV, was a novel form of population screening in the UK (Story 1). To measure whether this intervention would lead to earlier and greater diagnosis of HIV, an experimental research design accounting for interventions in their context of use, the pragmatic trial, was used (Story 2). The results of the RHIVA2 trial aimed to provide generalisable conclusions about the impact of the intervention and be applicable to other UK boroughs with similar epidemiological indicators.

#### **1.4 What's in a logic?**

The decision to describe the two stories told in this thesis as 'logics' was a considered one. What I required was a term that not only encompassed ideas and actions but described a patterning of thought and language along with bureaucratic processes, apparatuses and general orderings. I first came across this form of description in Annemarie Mol's *The Logic of Care* where she contrasts the 'logic of care' with 'the logic of choice' (2008). Mol uses the term logic to convey the 'rationale' of what she describes which is fitting to my objective here. Both the logic of normalisation for HIV, and the logic of the pragmatic trial contain a reasoning which the term 'logic' helps to depict by inviting 'exploration of what is appropriate or logical to do in some site or situation, and what is not. It seeks a local, fragile, and yet pertinent coherence' (Mol, 2008: p.10). The logics I describe emerged from, and are situated in, the work undertaken as a part of the PhD and while they structure the presentation of my findings, they also reflect them. My choice to tell the two stories in this way relates to my desire to locate the PhD project in the broader scenes of biomedicine. By presenting these two stories I hope to engage the reader in a way that enables them to consider the two logics as situated within, and related to, pertinent realities in the current organisation of biomedicine, disease and evidence.

#### **1.5 Study design, research questions and aims**

My work is nested within the RHIVA2 trial of rapid HIV testing in primary care. The trial took place over a 28-month period from 2010 to 2012. The PhD research followed the trial

and directly explores questions related to the experience of the trial. In attending to what took place throughout RHIVA2, the PhD and the overarching research question have a dual focus, attending to both the logics of the implementation mechanism (population screening for HIV and the logic of normalisation), and the evaluation of the intervention (RHIVA2 and the pragmatic clinical trial logic). The overarching research question can be summarised as:

**How did population screening for HIV become national policy (?), and to what extent could its implementation, through the RHIVA2 pragmatic randomised controlled trial, be regarded as successful (by participating practices and newly diagnosed patients)?**

The PhD project involved three sub-studies that take place at the policy, the general practice organisation and the patient level. Using a case study methodology, I trace the recommendation of HIV testing for newly registered patients in primary care from its policy origins to its enactment on patients. By exploring the basis of the policy, the lived experience of a trial which encompassed a potential mechanism for the enactment and demonstration of the policy, and the intervention's meaning for patients, I develop a fuller understanding of what policy enactment looks like in practice. The study context offered a unique opportunity to illuminate 'evidence creation' and notions such as the 'roll out' of interventions as a part of experimental research.

My aim is to make visible some of the complex social practices that are enacted in the design, conduct and evaluation of the RHIVA2 pragmatic trial and to broadly elucidate findings related to population screening programmes for HIV in the UK and the conduct of pragmatic trials, such as RHIVA2, more generally.

The policy study asks:

- a) How was HIV testing for all new registrants in general practice in areas where more than 2/1000 people are living with HIV justified as a national policy recommendation?
- b) What were the key interrelated discourses in operation in the policy community and policy documents at the time (2008-2011)?

The organisational study asks:

- c) In RHIVA2 trial intervention practices, what organisational level influences and interactions explain variation between practices in the uptake of rapid HIV testing?

The patient study asks:

- a) What are the experiences of patients undergoing rapid HIV test diagnoses in general practice as a part of the RHIVA2 trial and how did the trial become meaningful to them?
- b) How did the logics of normalisation and the pragmatic trial interact with patient experiences, and how did these experiences help produce the trial results?

## 1.6 Structure of the thesis

Following this *Introduction* is **Chapter 2: Background**, where I first explain my personal context for the work. I then describe the state of HIV in the UK at the time of the RHIVA2 trial, including HIV prevalence, treatment norms and contemporary public health priorities related to the infection. In describing the policy context, I introduce some relevant research undertaken in the UK including the RHIVA1 research, an acceptability and feasibility study preceding RHIVA2, and RHIVA2, the study in which this PhD is nested.

This is followed by **Chapter 3: Background to methods**, where I articulate my philosophical approach to the work with an essential outlining of ontology, epistemology and paradigm, as well as variable positions on the philosophical spectrum. This includes outlining six ‘sensitising concepts’ that have shaped my analytic approach: *the experiment, the surplus, dwelling in doubt and tension, novelty and being a beginner, pragmatism and experience*. Following this, in **Chapter 4: Methods**, I outline the main methods used for data collection. These include case study, qualitative interviews, process evaluation and auto-ethnography. I also describe discourse analysis as an analytic approach to textual data.

The findings of the thesis are presented in three parts. The choice to break the work down this way was made to assist readability and coherence. Each part includes a description of some relevant literature, the theoretical frame used to analyse the data and a summary of the data sources called upon in the analysis. The decision to break up the literature, theory and data sources in this way was out of consideration for the reader and a concern that frontloading the thesis with literature and theory would have made for a less cohesive presentation of the work. As a result, the thesis can be read in three parts. Each parts aims to build on the preceding and draw out the experience of the RHIVA2 trial from its conceptualisation as a way of evaluating and implementing policy (Part 1) through to its enactment in general practice organisations (Part 2) and its implications on patients and research conclusions (Part 3).

***Part 1: Population screening for HIV and the logic of normalisation***, presents findings from the policy-level study. I begin with a summary of some literature related to the sociology of screening and diagnosis and a description of data sources: 14 in-depth interviews with policy stakeholders and four key policy documents (***Chapter 5***). I then present two findings chapters (Chapters 6 and 7). Part 1 provides a ‘thick and theorised’ backdrop for the remainder of the thesis through a detailed consideration of the circumstances enabling the RHIVA2 trial.

***Chapter 6: An empirical study of the policy context for the HIV testing of newly registering patients in primary care in the UK***, explores a key policy document: the *UK National Guidance on HIV Testing 2008*, which contains the recommendation of considering HIV testing for all new registrants in primary care in high prevalence areas (defined at the time as where more than 2/1000 people are living with HIV). I seek to understand how this policy was justified and enabled. Through a combination of textual analysis of this policy document and in-depth interviews with members of the HIV policy community, I identify 17 themes across four broad categories I term ‘micro-streams’. The four ‘microstreams’ include: *public health and epidemiology, treatment technology and techniques, health setting factors and socio-cultural dimensions of HIV in the UK*. I draw on Kingdon’s policy windows framework (2003) and Wilson and Jungner’s principles for the early detection of disease (1968) to theorise the findings. This analysis shows that a policy window developed as the

result of a coupling between the ‘problems’ stream and the ‘policies’ stream related to Kingdon’s model. Epidemiological indicators regarding the late presentation of HIV as undesirable for individuals, populations and the economy created a pressing policy problem. The construction of undiagnosed HIV as a ‘problem’ was supported and enabled by stakeholders in the HIV policy community. Existing policy precedence within the UK and abroad, which included population screening approaches to HIV testing, were integral aspects of the ‘policies’ stream. New emphasis on primary care was facilitated by the availability, feasibility and apparent simplicity of rapid tests, abbreviated pre and post-test counselling, an emphasis on settings with access to the general population, and the cost-effectiveness of non-specialist health professionals offering HIV testing. The application of Wilson and Jungner’s principles for the early detection of disease revealed that HIV in its contemporary form broadly justifies population screening approaches in highly endemic areas.

In *Chapter 7: Screening for a ‘normalised’ HIV: A discourse analysis of policy documents and stakeholder interviews*, I present a discourse analysis of four key policy documents (BHIVA et al., 2008; NICE, 2011a; NICE, 2011b; HPA, 2011) and the 14 in-depth interviews. I explore how discourses circulating in the HIV policy community and key UK policy documents justify and uphold population screening approaches for HIV testing in UK general practice. It is here that Story 1: the logic of normalisation becomes more apparent. After identifying key discourses in the HIV literature and a subsequent analysis of the data set, three main discourses were identified. These include a *risk/surveillance* discourse, a *HIV normalisation* discourse and a *HIV generations and dynamism* discourse. The *risk/surveillance* discourse works to position the general population and undiagnosed HIV-positive individuals as the site of embodied risk for HIV. Biomedical advances in HIV care blur the boundaries between health and illness and the testing of asymptomatic individuals for HIV takes on heightened status. The *HIV normalisation* discourse presents a tension between the historic exceptionalism of HIV as a lethal infectious disease and its related practices in biomedicine and public health, and the new normalisation project which positions HIV as a chronic disease ‘like other medical conditions’. The normalisation discourse brings new forms, sites and practices of HIV testing into focus and primary care takes on new and increased responsibilities. The *HIV generations and dynamism* discourse positions HIV as historically situated and dynamic, with multiple enactments and states of infection that have required and continue to require varying, situated responses. HIV screening is met with

enthusiasm partially due to its prior prohibited status. The changing and multiple nature of HIV infection alters professional roles and identities around HIV care and impacts on professional relationships and policy making activities.

In ***Part 2: RHIVA2 in practice: Implementing and evaluating a complex intervention***, I explore the trial ‘in practice’ by theorising the variation of uptake in rapid HIV testing in RHIVA2 intervention practices. Here, the logic of normalisation and the logic of the pragmatic trial converge on site in a single London borough, highly endemic for HIV<sup>1</sup>. I begin with a description of methods and how contemporary research practice aims to account for complexity and context through a variety of methodological manoeuvres (***Chapter 8***). I then describe the data sources for the process evaluation<sup>2</sup>. ***Chapter 9: Explaining the variation of rapid HIV testing among RHIVA2 intervention practices using diffusion of innovations theory***, presents findings from the organisational-level empirical study. Using process evaluation methodology and the construction of four case studies, I explore the experience of health care providers and organisations taking part in RHIVA2. Using Greenhalgh et al.’s model of ‘diffusion of innovations in health care settings’ (2004), I consider what factors led to the uptake and successful implementation of rapid HIV testing in some practices and what factors impeded uptake in others. I retrospectively compile quantitative data in the form of testing and diagnosis rates, practice level data such as the size and staffing of participating practices and qualitative data in the form of 21 semi-structured interviews with health care professionals providing rapid testing. The application of the model reveals that successful practices (those able to offer many rapid HIV tests) appear to be innovative practices. These practices demonstrate good managerial relations, readiness for change and a culture of staff training and support. Here, adopters appear personally motivated and see the value of the innovation to the patient population. In these settings local adaptations to the innovation helped embed the new practices into organisational routines. Early experience of a reactive rapid HIV test appeared to reinforce a commitment to testing.

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<sup>1</sup> Highly endemic of HIV in this case refers to the definition outlined in the 2008 National Guidance, where greater than 2/1000 people with known HIV status reside in the borough (BHIVA et al., 2008).

<sup>2</sup> The findings presented in Part 2 were also published as a paper: *Explaining high and low performers in complex intervention trials: a new model based on diffusion of innovations theory*, by myself and colleagues in the journal *Trials* in 2015. The research was undertaken as a part of the PhD project. This is acknowledged in the chapter itself as well as on the statement of originality provided at the beginning of the thesis.

Practices with less successful implementation of rapid testing had less good managerial relations, significant resource and time constraints and some key staff appeared less comfortable with the test. No early positive results were evident in these practices. The adapted diffusion of innovations model, as applied retrospectively to explore the RHIVA2 trial, was an effective method of investigating and explaining the variation in uptake of rapid testing in RHIVA2.

In *Part 3: Experimental end-points: Patient experience and the pragmatic trial*, I shift focus to the HIV-positive patient, as detected by rapid testing, and to the logic of the pragmatic trial more explicitly. A successful trial and patients with HIV diagnoses were the anticipated end points of the RHIVA2 trial and, to some extent, the 2008 National Guidance policy recommendations. I explore how the trial became meaningful to patients and therefore how RHIVA2 produced statistically significant results. These results support the policy recommendations and achieve the broad objective of greater detection of HIV in the UK. It was at this point in the PhD work that a deeper engagement with theoretical literature felt necessary to describe the tensions the data was surfacing. It follows that I begin with a discussion of some literature from the fields of science and technology studies, the philosophy of science, and anthropology (*Chapter 10*). I then describe the data sources before presenting two findings chapters.

*Chapter 11: Producing difference in RHIVA2: HIV-positive patient experiences of rapid testing*, calls upon five in-depth interviews with patients testing HIV-positive, with the first test being a rapid HIV test as a part of RHIVA2. I first explore experimentality through the work of philosophers of science, Hans-Jörg Rheinberger and Vinciane Despret and consider RHIVA2 and the rapid HIV test as devices aiming to detect ‘difference’ (Rheinberger, 2015; Despret, 2004). Analysis of the five patient cases reveals that rapid testing in RHIVA2 becomes (to some extent) meaningful to patients through the trial’s ability to respond and attune to patient questions and subjectivities. The normalising technology (Philbin, 2014) of HIV screening in general practice allows for patients to interact with testing in a ‘normalised’ fashion; however, post-diagnosis secondary care services appear as spaces where HIV infection is ‘less of a big deal’, and are experienced as more ‘normalising’ for patients. Patient accounts also present challenges to the trial’s construction and presentation of



patients, with implications for the reporting of trial findings. This is taken up in the following chapter where I explore findings related to the pragmatic trial logic.

**Chapter 12: Considerations of the pragmatic trial**, draws on various data sources from my empirical work and offers methodological reflections. It is here that the logic of the pragmatic trial is described and explored more overtly. Calling on theory from philosophy and anthropology (Kelly, 2008; Savransky and Rosengarten, 2016; Viveiros de Castro, 2004; Mol, 2002) and dialogically engaging the experience of the trial with different methods and epistemological assumptions allows for varying accounts of the research events to come forward, which have implications for the claims of the pragmatic trial design and the presentation of findings from RHIVA2. In the attempts of the pragmatic trial design to account for the ‘real world’ while seeking to provide ‘gold standard’ evidence much transpires. I outline how the logic of the pragmatic trial occludes much of the ‘work’ the pragmatic trial does in accounting for the ‘social’. The pragmatic trial appears as a productive device that is to some extent successful at merging the ‘gold standard’ methods of the RCT design with the complex and situated world of everyday clinical practice. Two data fragments, written up as cases and termed ‘ambiguities’, illustrate how the method is unable to account for this partial success within the restrictive evaluation and reporting methods of the pragmatic trial design. While the method is designed to produce clear, generalisable answers to complex research questions about the ‘real world’, my analysis shows that while the experimental design may produce such data, they are not always recognisable by the method and may remain unaccounted for. This has profound implications for determining the mechanisms of ‘successful’ interventions and the generalisability and reproducibility of trial findings.

Parts 1, 2 and 3 are followed by the **Discussion** in **Chapter 13**. Here I summarise the findings from the policy, provider and patient level analysis. I provide broad and overarching reflections on Story 1: the logic of normalisation for HIV, and Story 2: the logic of the pragmatic trial as well as the resonances and tensions between the two stories. I then comment on the research process and some of the unique contributions of this research. This is followed by recommendations for further research based on the findings uncovered in the PhD.

**Table 1.** A guide to the research questions, methods and data sources

<b>A guide to Parts 1, 2 and 3</b>				
<b>Sub- Study</b>	<b>Research Questions</b>	<b>Method</b>	<b>Theoretical Frame</b>	<b>Data Sources</b>
<p>Part 1: Population screening for HIV and the logic of normalisation  (Policy-level study)</p>	<p>a) How was HIV testing for all new registrants in general practice in areas where more than 2/1000 people are living with HIV justified as a national recommendation?  b) What were the key interrelated discourses in operation in the policy community and policy documents at the time of the RHIVA2 trial (2008-2011)?</p>	<p>a) Content analysis of 1 key policy document and 14 interviews with policy stakeholders  b) Discourse analysis of policy documents and interviews</p>	<p>a) Kingdon’s policy windows theory (2003) and Wilson and Jungner’s principles for the early detection of disease (1968)  b) Parker’s method of discourse analysis (as adapted by Shaw) (2009) with reference to existing discourses in the HIV literature</p>	<p>1) Interviews with 14 stakeholders in the HIV policy community  2) Four key policy documents  3) Ethnographic field notes collected over 100 hours spent on site in RHIVA2 intervention practices</p>
<p>Part 2: RHIVA2 in practice: Implementing and evaluating a complex intervention (Organisational-level study)</p>	<p>a) What factors impacted the variation of offer in HIV testing as a part of the RHIVA2 trial of rapid HIV testing in primary care amongst intervention practices?</p>	<p>a) Process evaluation</p>	<p>a) Greenhalgh et al. model of the diffusion of innovations in health care organisations (2004)</p>	<p>1) 21 interviews with 23 providers of rapid HIV testing as a part of the RHIVA2 trial  2) Trial data in the form of numbers of tests performed and diagnoses made  3) Ethnographic field notes collected over 100 hours spent on site in RHIVA2 intervention practices  4) Practice level data – list size, practice location etc.</p>
<p>Part 3: Experimental end-points: Patient experience and the pragmatic trial (patient-level study and all findings synthesis)</p>	<p>a) What are the experiences of patients undergoing rapid HIV test diagnoses in general practice as a part of the RHIVA2 trial and how did the trial become meaningful to them?  b) How did the logics of normalisation and the pragmatic trial interact with patient experiences and how did these experiences help produce the trial results?</p>	<p>a) Thematic analysis of in-depth interviews with patients  b) Synthesis of methods and analysis - pulls on all methods and data sources</p>	<p>a, b) Theory emerging from science and technology studies and philosophy of science including Rheinberger (2015) and Despret’s (2004) and Mol’s work on experimentation and multiplicity (2002) and Savransky and Rosengarten’s work on RCT ontology (2016)</p>	<p>1) Five in-depth interviews with HIV-positive patients (out of a possible 11) diagnosed as a part of RHIVA2 with the first test being a rapid HIV test in an intervention practice  2) Synthesis of methods and analysis – including trial results, interviews with patients and providers, ethnographic field notes and trial documents</p>

## **Chapter 2: BACKGROUND**

This PhD is based upon the experience of the RHIVA2 trial of rapid HIV testing in primary care. RHIVA2 was established to evaluate and implement the national HIV testing recommendations outlined in the 2008 National Guidance, which recommended men and women in areas where more than 2/1000 people were known to be living with HIV should be considered for an HIV test at the point of registration with general practice (BHIVA et al., 2008). In this chapter I will describe some of the broader research and policy context for the recommendations and therefore the trial. I also describe how the questions addressed in this PhD became relevant to me in my then role as trial manager for RHIVA2 and what inspired my interest in this work. I now present my personal context, the policy context and the RHIVA studies.

### **2.1 My personal context**

The immediate context for this PhD is my work on the RHIVA2 trial. For nearly three years, I acted as a research assistant and then as the trial manager of the study. With a background in sexual and reproductive rights and having completed an MSc in research methods, investigating HIV testing in highly endemic areas interested me, I saw the trial as a useful way to apply what I learned in the MSc. HIV appears to me as a highly social and dynamic infection with a fascinating history and unpredictable future. The way HIV and its implications transition and play out in medical, social and political realms has always intrigued me, not least after having lost a family member to the infection shortly before anti-retroviral drugs (ARVs) became widely available. I was also interested in how we might determine evidence and measure the effectiveness of interventions. Having worked for many years in social programmes among young people with complex life circumstances, as well as in international development with distant and politically charged issues, I was curious about how to measure social phenomena, account for complexity and establish an 'evidence base'. I was often struggling to find funding for complicated social programmes that I believed were effective and important and I wanted to know how to produce 'evidence' to convince the funders.

As a teenager I worked with six close friends on a programme for young women entitled ‘Revolution Girl Style’. In my community, a remote city in northern Canada, with a number of complex social problems, our programme was strongly personal and political. Through the development of a summer camp for girls aged 11-17 we promoted self-esteem and leadership, deconstructed our experiences using our budding knowledge of feminism and politics, and promoted health and well-being. When two of our programme leads unexpectedly became parents it troubled what I thought was an effective ‘health promotion technique’. Our programme included sessions on sexual health, contraception and essentially many aspects of what would fall into the understood category of ‘prevention’ regarding young parenthood. Our funders were indeed interested in reducing unplanned conceptions as a programme outcome. I wondered if our programme had failed.

Over time, as I sat with my friends throughout their pregnancies and early motherhood it was clear that the skills and resources which formed a part of our programme were mobilised throughout their pregnancies and onwards in perhaps unexpected ways. They managed motherhood in a manner contrary to the perceived young parent norm. For example, they drew on formal and informal local resources, actively participated in on-line forums, used feminist approaches to birth, continued with education, and essentially evaded much of what causes us to understand young parenthood as a social problem. If our programme was evaluated on reducing conceptions alone it may have been considered a failure. I wondered however if my friends’ decisions to keep their children (what they really wanted, both were pro-choice) and their manner of managing their unexpected pregnancies possibly demonstrated programme benefits? While this is hard to say, what became clear to me was how what we measure matters, as do the questions we ask and the research outcomes we choose and value.

I did not imagine finding myself eventually managing an RCT. The questioning that began through considering our young woman’s programme stuck with me throughout the process of the trial. In my role as trial manager I was involved at most levels, from the research design meetings down to everyday trouble shooting with practice health care assistants and even acting as a ‘simulated patient’ where I underwent numerous HIV rapid tests. Throughout the 28-month trial I consistently questioned our actions and approaches. I wondered about the

limits of the pragmatic design and how ‘pragmatic’ to be, what constituted the ‘real world’, and how and why we place so much trust in statistical methods. I wanted to better understand how we determined RCTs as the ‘gold standard’ and how contrasting data and other forms of ‘knowing’ were approached in academia.

When I started the PhD we did not know the results of the RHIVA2 trial and the research team felt unclear as to whether the intervention was ‘effective’ or not. During the trial period the National Institute of Health and Care Excellence (NICE) released guidance supporting the recommendations evaluated in the trial, further establishing this approach as national guidance (NICE, 2001a; NICE, 2001b). The adoption of opt-out testing as national policy and the positive results of the trial made the PhD research questions highly topical. In the face of a statistically negative trial we would have been looking for explanatory factors and troubling approved national guidance. While the contextual aspects of trials are often explored to explain non-statistically significant trial findings, positive trials also contain all the variables explored in the instances of ‘failure’. Throughout the trial, our experiences, perceptions and rough calculations were not leaving us with clear impressions about the intervention. Some would say this is a good thing, because as researchers we should be neutral and unsure. However, post-statistical testing, rapid HIV testing as done in RHIVA2 was deemed a ‘success’ and suddenly the need for explaining appeared diminished if not redundant. It was assumed the trial had located the ‘active ingredients’ that make the complex intervention of rapid testing in general practice successful and that the protocol could ‘plug and play’ in a similar setting.

Despite feeling relief at the success of the intervention I felt unsatisfied with the conclusion as presented in formal reports of the trial. It seemed reductive in the face of everything that had transpired in the process. Much of what was observed is not presented in the published trial findings and there were information and complexities that seemed overlooked. In the case of our trial and the small number of patients with reactive rapid HIV test results, a positive finding (that is, the finding that point-of-care HIV testing in UK general practice significantly increased the number of people identified with HIV at a treatable stage) hung on very few patients to produce the statistically significant results. As a result, this PhD explores the ‘surplus’ (see opening quote on page 10) that is, information that never acquired the status

of ‘data’ in the logic of the trial. I hope to open up the trial and the intervention to learn more about how these results were produced as well as what it means for patients and providers to offer HIV testing in this way. These tensions present the personal and professional setting for the work reported here.

## **2.2 The policy context**

### *HIV testing in the UK*

At the time of writing, approximately 104,700 people are living with HIV in the UK (PHE, 2015). In 2008 it was estimated that 83,000 people were living with HIV in the UK and that one third of these infections remained undiagnosed (BHIVA et al., 2008). Of those newly diagnosed, approximately 25% were presenting at a late stage in the infection<sup>3</sup> (BHIVA et al., 2008). In the UK, two broad groups are consistently considered to be at ‘high risk’ for the contraction of HIV: men who have sex with men (MSM) and black Africans (NICE, 2011a; NICE, 2011b).

Since AIDS was identified in 1982 (AIDS Gov., 2016), there have been constant transitions in the treatment possibilities and health care innovations surrounding the infection. The virus has been recognised as a truly ‘biosocial’, where biological and social factors interact to generate variable forms of living with HIV (Persson et al., 2014). The speed, scale and dynamism of the clinical, social and political picture of HIV have led many to consider it an epidemic unlike any other, garnering levels of unprecedented scientific, social and political mobilisation (Persson, 2013; Smith and Whiteside, 2010). Presently, it is possible to be living well with HIV infection. When individuals are aware of their HIV-positive status and able to access and adhere to treatment, survivorship dramatically increases and the potential for virus transmission decreases. As a result of developments in the detection and treatment possibilities for HIV, greater emphasis has been placed on testing, particularly at an early stage, to improve life expectancy, reduce transmission and conserve health care resources (BHIVA et al., 2008).

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<sup>3</sup> Late presentation for HIV is defined as a stage where CD4 count is less than 350 cells/ $\mu$ l or presenting with an AIDS defining illness. Very late detection or advanced HIV disease is defined as a stage where the CD4 count is less than 200 cells/ $\mu$ l (Antinori et al., 2010)

In 2008 the British HIV Association (BHIVA), the British Infection Society (BIS) and the British Association for Sexual Health and HIV (BASHH) produced UK national guidance on HIV testing entitled the *UK National Guidelines for HIV Testing 2008* (2008 National Guidance). Amongst these recommendations was the promotion of opt-out HIV testing for newly registered patients in primary care in areas where more than 2/1000 people are living with HIV. Increased testing of individuals accessing primary care services was recommended as a way of decreasing the late detection of HIV, reducing health care spending, and lessening mortality, morbidity and virus transmission (BHIVA et al., 2008). This recommendation informed the RHIVA2 trial and is an important aspect of the findings reported here, Part 1 of this PhD explores this guidance in depth.

These recommendations reflected, and were concurrent with, a number of advances in HIV science. Of prime importance was the finding that treatment can act as prevention by reducing the HIV viral load present in an individual to undetectable levels, therefore significantly lowering the likelihood of transmitting the infection (Cohen et al., 2011). The evidence base to support this claim was established with the 2011 publication of the landmark HPTN 052 study (Cohen et al., 2011). However, the HIV community had been attentive to these developments since at least 2008 with ‘The Swiss Statement’ (Vernazza and Bernard, 2016; Vernazza et al., 2008). This statement indicated that ‘An HIV-infected person on antiretroviral therapy with completely suppressed viraemia (“effective ART”) is not sexually infectious, i.e. cannot transmit HIV through sexual contact.’ (Vernazza et al., 2008: p.1). This statement was said to hold if:

- the person adheres to antiretroviral therapy, the effects of which must be evaluated regularly by the treating physician, and
- the viral load has been suppressed (< 40 copies/ml) for at least six months, and
- there are no other sexually transmitted infections.’ (Vernazza et al., 2008: p.1)

Despite these positive developments, the treatment possibilities for HIV vary internationally, meaning care and nuance is required when broadly discussing HIV. The consideration of HIV as a chronic treatable medical condition is only possible in the context of treatment and access to medical care, otherwise HIV remains the deadly condition experienced in the UK

throughout the eighties and early nineties. Despite access to free specialist medical services for HIV through the National Health Service (NHS) an individuals' experience of HIV in the UK is highly variable and it is widely acknowledged that social and cultural factors strongly influence an individual's ability to equally access and benefit from such services. Social support, poverty, multi-morbidities and other factors impact upon an individual's ability to live well with an HIV-positive status (National AIDS Trust, 2014; Hodgson, 2014).

Rapid, 'near patient' testing, where a test is carried out in close proximity to the patient and the results are provided within minutes, has been proposed as significantly advantageous for reasons including its portability, accessibility and speed (Prost et al., 2009). Patients may be tested in more diverse locations, by a greater number of providers, and are likely to receive their diagnosis more quickly and easily. Rapid delivery of HIV-negative results is also considered valuable by providing an opportunity for health education and by encouraging a 'know your status' approach to HIV infection (National AIDS Trust, 2016).

Correspondingly, rapid HIV testing is now offered in non-clinical setting by individuals with variable levels of expertise. Such locations include community spaces such as churches, and additional medical settings such as dermatology clinics and accident and emergency units (Rayment et al., 2012). More recently, HIV testing is available at home with self-testing initiatives and the legal commercial sale of HIV testing kits (Stephens, 2014).

While HIV testing has been available in general practice since early in the history of HIV, the manner of delivering testing has seen various transitions. Rapid testing is relatively new to general practice in the UK and the routine offer of an HIV test to all new registrants in highly endemic areas, as suggested in the 2008 National Guidance, represents a new mode of offer.

While such tests are considered simple to use and implement in various settings, their use has social meaning and alters practices, relations and diagnostic experiences. Practices surrounding testing are in constant adaptation to testing and treatment technologies, making HIV a dynamic infection with multiple enactments influenced by location and circumstance (this will be further discussed in Part 1 of the thesis). Rapid testing is possible due to a long history of developments in science, technology, treatment, activism, policy, and patient



experience. The way in which it is acceptable for individuals (not always patients) to be offered a test exemplifies these changes. The reduced emphasis on pre and post-test counselling for HIV provides an example as it was once considered best practice and an essential activity to accompany the offer of a HIV test. Since 2008, at least in some settings, pre and post-test counselling has been discouraged and is regarded as time-consuming and a hindrance to efficient testing (BHIVA et al., 2008; Cohan, 2009).

### *Population screening approaches for HIV*

Screening can be defined as ‘a testing strategy that involves testing persons regardless of whether they have a recognised behavioural risk or presence of signs or symptoms of infection.’ (CDC, 2011: p.4). A characteristic of screening is that it is population based and may involve all individuals in a population or all those with a specific characteristic and tends to involve little interaction with patients in determining whether to offer a test (CDC, 2007b). Population screening for HIV is not an official screening programme endorsed by the UK National Screening Committee (UKNSC). Despite this, the offer of routine opt-out testing for HIV to new registrants in a highly endemic borough, as was recommended in the 2008 National Guidance, constitutes a population screening approach to HIV testing. This method of offer is in contrast to previous HIV testing approaches, which have typically been ad hoc, triggered for example by patient characteristics or behaviours or by morbidity, such as a presentation of indicator conditions for HIV infection such as pneumonia or shingles (BHIVA et al., 2008).

In an attempt to diagnose HIV infections and initiate those testing HIV-positive on treatment, a push for routine testing of new registrants in primary care settings began in September 2006 with the Centers for Disease Control and Prevention (CDC) in the United States. This followed on from policy shifts in 2001 when the CDC altered the protocol for pre and post-test counselling, in an attempt to reduce barriers to testing (Branson et al., 2006). They also recommended screening high risk patients at least annually, removed the requirement for written consent for HIV testing, added HIV to the routine testing panel for pregnant women, and proposed third trimester screening in highly prevalent areas (Branson et al., 2006). Importantly, the CDC also indicated that wherever possible HIV testing should be opt-out (Branson et al., 2006). See the recommendation below:

‘In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13–64 years. Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.’(Branson et al., 2006: p.4)

These recommendations marked a distinct shift away from earlier best practice. This international precedence set by the CDC made way for more accessible and widespread HIV screening programmes, particularly in high resource settings.

A similar policy was promoted in the UK in 2008 when BHIVA issued the aforementioned guidance indicating that in all areas where more than 2/1000 people were living with HIV, testing should be considered for all new registrants in general practice – the 2008 National Guidance (BHIVA et al., 2008). It was this guidance that the RHIVA2 trial implemented and evaluated. The National Institute for Health and Care Excellence (NICE) echoed the recommendations in 2011, following a series of pilots conducted by the Health Protection Agency (HPA) (HPA, 2011; NICE, 2011a; NICE, 2011b). At this time the RHIVA trial was already underway. In 2008, 42 of the 152 local authorities across England had a diagnosed HIV prevalence greater than 2/1000 in 15-59 year olds and the policy was seen as a potential solution to the stated problems of undiagnosed HIV and late detection (PHE, 2014).

In an aim to bolster the evidence base and explore the feasibility and acceptability of new modes of HIV testing in the UK national funding from the Department of Health (DoH) was granted to support pilots of HIV testing in non-traditional (largely community and A&E) settings. Separate to these DoH funded pilots was a small Medical Research Council (MRC) - funded feasibility study of HIV testing (RHIVA1), which took place in a single general practice in a borough highly endemic for HIV. A member of the RHIVA2 study team was a GP at this practice, and had just completed a borough-wide trial of screening for tuberculosis (Griffiths et al., 2007). This GP became the principal investigator of the RHIVA2 trial after collaborating on RHIVA1 and proposing a trial testing the impact of HIV testing in primary care – the RHIVA2 trial. The main funding source for the RHIVA2 trial was the public health unit in the borough in which the trial took place. An academic primary care team at

Queen Mary University of London (QMUL), further elaborated the design of RHIVA2 with the director of public health, in collaboration with a consultant at the Department of Sexual Health at the local hospital. The RHIVA studies will be further described later in the Chapter (See section 2.4).

At this time, the HIV policy climate was one of experimentation and curiosity about the potential of population screening approaches to HIV. A push of research on HIV testing in ‘non traditional settings’ using new tools such as rapid tests was taking place across Britain with findings beginning to roll in and add shape to the UK HIV policy scene.

### **2.3 The UK policy and research context**

In this section, I will briefly describe studies relevant to the policy context of RHIVA2 in the UK. In 2009 and 2010 the HPA took on a number of pilots related to HIV testing outside of specialist settings. Eight projects explored the expansion of HIV testing in the UK. All pilots had observational, non-experimental (uncontrolled) designs. Specific emphasis was placed on non-traditional settings and diverse testing models. Two pilot studies were held in primary care settings. Over an 8-month period in Brighton and Hove (where the HIV prevalence was 7/1000), finger-prick rapid testing was offered to new patients aged 15-59 in 10 general practices. Patients were also asked to complete a questionnaire regarding their experience. 2478 tests were offered with 1473 performed and two patients were identified as HIV positive. Practices were paid £500 to participate and £20 per test or questionnaire completed. Practice variation in offering tests ranged from 17% to 88% of eligible participants. The majority (88%) of patients found rapid testing acceptable as part of a new patient check. The research team concluded that the successful extension of testing was dependent on various factors including practice-level adaptation to variations on the new patient check as well as sufficient training and support for clinicians offering testing (HPA, 2011).

In Lewisham, a similar pilot took place. The known HIV prevalence was 5.88/1000 in 2008. Of the 48 practices invited, 18 participated. Practices were paid £5 per test performed. Over 9 months 2,713 patients had INSTI tests, it is unknown how many were offered. Of these, 19

patients were detected as HIV positive and one patient experienced a false reactive result. Of the 19 positive results, 5 were diagnosed at a walk in centre and not as part of the regular new patient check, 4 never transitioned into secondary care and most never revisited their GPs. The pilot highlighted challenges with data collection and estimated that INSTI testing adds one to five minutes of additional time onto a consultation (HPA, 2011).

Overall, the pilots were viewed as a success and encouraged the push for the routine offer of testing, citing the rapid point of care method as an effective means. Cost analyses applied to the pilot data also allowed for estimates for endorsing routine testing of new patients in high prevalence areas as national policy. Estimates were placed at £1.6 million for the national roll out of routine rapid testing, at an average of £8 per test (HPA, 2011) A number of letters of support and news articles began to appear in publications such as the British Medical Journal (Gulland, 2011; O'Dowd, 2011)

On September 1st, 2011 the House of Lords Select Committee on HIV and AIDS in the UK backed calls for the expansion of opt out testing (Select Committee on HIV and AIDS in the United Kingdom, 2011). Later in 2011, NICE issued clinical guidelines on the routine screening of new patients in primary care in high prevalence areas. This was contained within specific guidance for enhanced testing of high risk populations including men who have sex with men and black Africans (NICE, 2011a; NICE, 2011b).

As the UK adopted clinical guidance on HIV screening in general practice and explored the data produced from the pilots, the RHIVA2 trial continued, enacting the policy in the form of rapid testing for new registrants.

## 2.4 The RHIVA studies

### *The RHIVA1 feasibility and acceptability study*

The RHIVA1 study was designed to assess the acceptability and feasibility of offering rapid HIV tests to patients registering with primary care in a London borough with a high prevalence of HIV. The study took place in 2007 and 2008 and was led by a single researcher. The RHIVA1 study aimed to determine whether the recommendation from the 2008 National Guidance was feasible and acceptable both to patients and the primary care setting and test the rapid testing mechanism.

The study took place in one large and diverse general practice in a highly endemic borough. Over a 6-week period all Anglophone and Francophone registrants between 18 and 55 were invited to participate in the study by undergoing a rapid HIV (saliva) test as a part of their new patient registration (Prost et al., 2009). Throughout the research period there were 111 new registrants, of whom 85 were eligible for rapid HIV testing. Of the 38 who agreed to have a rapid test, one patient had a reactive rapid HIV test which was later confirmed as HIV positive (Prost et al., 2009). Patients were asked their reasons for declining or accepting tests and were also invited to participate in semi-structured interviews to explore their feelings regarding the acceptability of rapid testing in primary care, 20 patients agreed. The study demonstrated that black African and black Caribbean participants were more likely to accept rapid testing than patients from other ethnic groups (Prost et al., 2009). This was seen as positive as black Africans remain a 'high risk' group for infection and late diagnosis (NICE, 2011b). Participants listed a number of reasons for accepting and declining testing including: not being presently at risk, having recently had a test, being offered as a part of a routine check, reducing waiting times for results and the reduced stigma of attending general practices versus sexual health centres (Prost et al., 2009).

Despite the overall positive acceptance of rapid testing, patients outlined some potential disadvantages, including the speed of the test, meaning patients may not feel adequately prepared for their results, inappropriate support for the newly diagnosed due to the primary care setting, the accuracy of the test and a concern regarding false reactive results and feeling that perhaps the test should be offered to patients who requested testing or on the

recommendation of the GP. All felt that the GP should be the professional who shares results with patients (Prost et al., 2009)

The qualitative and ethnographic work in RHIVA1 revealed key challenges for implementation around the sharing of the test result, appropriate quality assurance and the time and space to adequately offer testing. Overall, the research concluded that rapid HIV testing is feasible and acceptable during registration health checks within general practice settings. The offer of rapid testing in this way was recommended with caveats to ensure best practice, including quality assurance procedures, psychological resources for new patients, guidelines regarding patient confidentiality and clear referral pathways into secondary care (Prost et al., 2009).

### ***The RHIVA2 study of rapid HIV testing in primary care***

The RHIVA2 trial of rapid HIV testing in primary care followed the RHIVA1 study and aimed to further investigate the impacts of offering rapid HIV testing to new registrants in primary care settings in an experimental fashion. Now that rapid testing had been shown to be feasible and acceptable in general practice, the trial aimed to determine if it was effective in diagnosing HIV at an earlier stage in the infection and in greater numbers. At the time of the trial there was an acknowledged lack of quantitative, high quality evidence regarding the effectiveness of the HIV screening guidance being promoted by BHIVA and the CDC. The trial aimed to contribute to the evidence base regarding HIV screening and to potentially add weight to the recommendations in the form of 'gold standard (randomised trial)' evidence. The pragmatic cluster RCT design was chosen due to the desire to see how rapid testing worked in its context of use. In a cluster design, units such as hospitals or schools are randomised rather than individuals but analysis may still be at the individual level (Eldridge, 2010). The cluster design was chosen for various reasons. There was concern regarding the cooperation of general practices, in that practices asked to offer testing to some patients and not others may find the intervention unethical. Administratively, it is easier to deliver the intervention by organisation than by individual, speaking to the pragmatic design of the trial (rapid testing would normally be a practice-level decision). Contamination was also

considered, as once practitioners are trained in offering rapid testing, they can't 'unlearn it' and may feel conflicted offering testing to some patients and not others, additionally they may be 'thinking HIV' more than previously if a new HIV intervention is present in the practice, which may alter other HIV testing practices (Leber et al., 2015 personal communication, February 5).

Over a 28-month period the trial took place in the same borough as the RHIVA1 study; 40 of a possible 45 eligible practices agreed to take part and were randomised to either intervention or control arms. Intervention practices were trained to offer opt-out rapid HIV testing to newly registering adults whereas control practices continued with care as usual. The primary outcome was CD4 count at diagnosis, an indicator of the stage of HIV infection. The secondary outcome measures included the number of new HIV diagnoses, expressed as a rate, and the percentage of patients with a CD4 count less than 350 and 200, indicators of infection stage<sup>4</sup>.

The intervention in RHIVA2 was not solely rapid testing, rather a complex, multifaceted educational programme for practice teams, promoting rapid testing. As described by a participant in the research presented here, rapid testing is a 'cluster'; testing in this way has consequences for practice roles and algorithms. Intervention practices received a 90-minute training session, delivered by me with a colleague (usually the local HIV nurse and occasionally a research team member GP or consultant). The training comprised theoretical elements (the rationale for the study, HIV as a public health problem and so on) and a practical element (rehearsing phrases, practising rapid testing). I often acted as a simulated patient or hired a community member to do so. In order to be able to offer rapid testing, intervention, practice staff were required to attend the training and perform three rapid tests, two on a person and one with a serum sample that would indicate the presence of HIV-positive antibodies. These three practice tests were to be undertaken using the appropriate phrasing and with correct interpretation of the results. If problems arose, I would usually

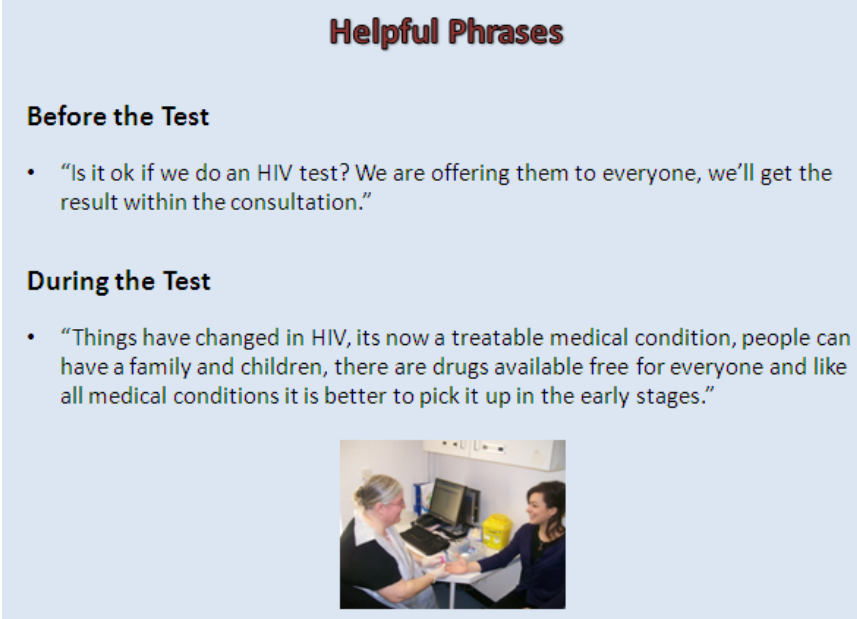
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<sup>4</sup> The outcomes were changed mid-trial with the approval of the data monitoring committee as it was discovered the original sample size and subsequent power calculations had been incorrect. This meant that the initial primary outcome, increased diagnosis of HIV, was no longer feasible. What had originally been a secondary outcome – CD4 counts indicating stage of diagnosis – became the primary outcome (Leber et al., 2015).

spend time re-training and undertake more practice tests. To assist study coordination, practices would select a lead for the RHIVA2 study, this was a nurse or health care assistant (HCA). Training in quality assurance activities and research algorithms would take place with the practice lead at a separate one-hour session, led by me. I would also administer a competency ‘quiz’ during this session and discuss any incorrect answers with the lead. Quality control procedures took place monthly for the first year of the trial and every three months for the remaining 16 months. I installed dedicated ‘read codes’ on clinical computer systems at the intervention practices. This was the mechanism with which the trial team captured practice-level performance data, meaning an additional component of intervention practice induction to the trial was inserting test results onto clinical electronic system templates.

Rapid testing was to be offered as part of the new patient health check without any questions to patients about their risk factors for HIV. The main phrasing taught in the RHIVA2 training is show in Figure 1 below, in the reproduction of a slide from the GP training slide deck.

*Figure 1. Phrasing from the RHIVA2 GP education session training slide deck*




**Helpful Phrases**

**Before the Test**

- “Is it ok if we do an HIV test? We are offering them to everyone, we’ll get the result within the consultation.”

**During the Test**

- “Things have changed in HIV, its now a treatable medical condition, people can have a family and children, there are drugs available free for everyone and like all medical conditions it is better to pick it up in the early stages.”



The new patient health check is a means to collect baseline health and lifestyle data on new registrants *via* standard questions. These are often led by computerised prompts, which is



where the RHIVA2 electronic template was added. Raising the possibility of HIV to a patient during a new patient check represents a new method of offering HIV testing in the UK. To a degree, this alters the nature of the appointment, as diagnostic testing is not normally a part of new patient registration checks. In the case of giving reactive<sup>5</sup> test results to patients, suggested phrasing was also provided. This will be further discussed in Part 2 and Part 3 of the thesis, where both provider and patient experiences of rapid testing are further explored. Importantly, the RHIVA1 feasibility study indicated that reactive test results should be shared by the GP (Prost et al., 2009) and this was adopted in RHIVA2; providers of rapid testing were taught to immediately contact the GP if the rapid test was reactive, to ensure appropriately trained staff were sharing the results.

A complex intervention is described as an intervention that contains several interacting components (Craig et al., 2008). Such interventions contain multiple elements and evaluations often aim to determine which ‘active ingredients’ make such interventions effective (McMullen et al., 2015). It is easy to conceptualise the intervention rolled out in RHIVA2 as solely the rapid test device. However, as described above, the test is enmeshed in context, as a part of the new patient health check to be delivered by HCA’s and nurses and in the primary care setting. Additional aspects such as quality assurance, the insertion of results systematically into electronic system templates, and communication, both with the research team and onwards, also formed a part of the intervention. So while rapid testing may appear simple and easy to use, the confluence of activities and contextual aspects surrounding the test add to the complexity, as does the fact the test aims to identify HIV, which remains a highly stigmatised infection.

### ***The rapid test***

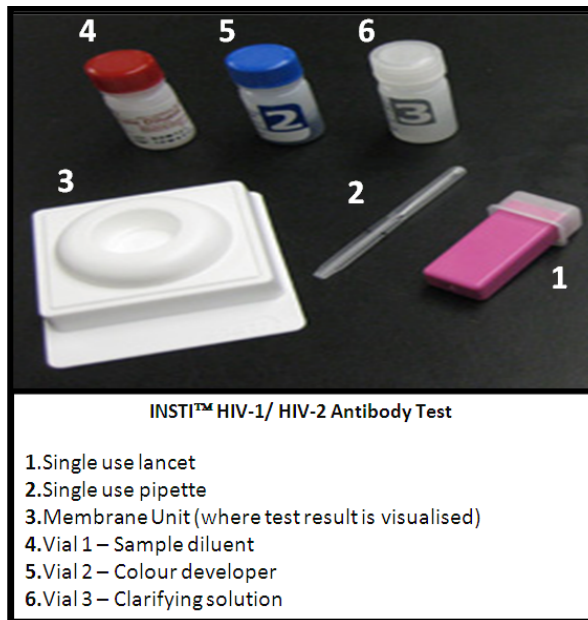
The INSTI™ HIV-1/ HIV-2 antibody test was the rapid point of care test used in the RHIVA2 trial. This single use rapid assay for the detection of antibodies to HIV virus types 1 and 2 is

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<sup>5</sup> A reactive test on the INSTI™ test device indicates that there is a likelihood of HIV infection. The term ‘positive’ is not used at this stage, as the test requires a definitive, confirmatory serology test.

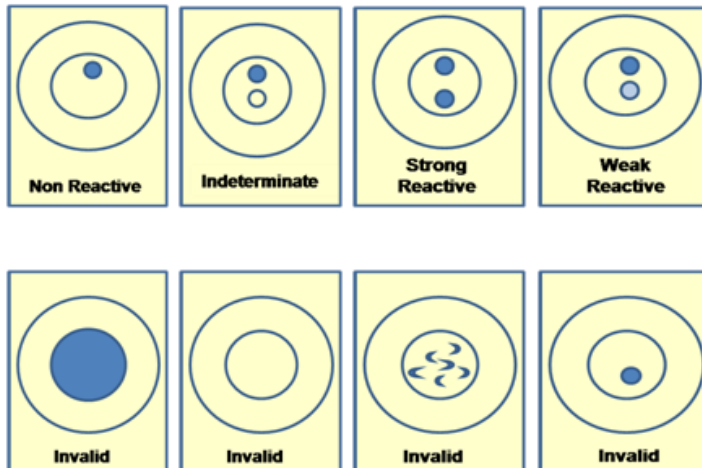
a 1-minute point of care rapid HIV test developed by bioLytical Laboratories and sold in the UK by Passante pharmaceuticals.

**Figure 2.** The rapid testing kit used in RHIVA2



The test requires 50 µl of finger-prick blood to produce a result. The test kits come as a single packet including all the material elements required to perform the test on an individual. This includes a lancet, pipette, a membrane unit which will display the result and three vials of fluid including a sample diluent, colour developer and clarifying solution. All materials are single use. The finger is pricked with the lancet and blood is drawn into the pipette, the blood is then emptied from the pipette into Vial 1, the sample diluent. This vial is then closed and shaken before being poured onto the well of the membrane unit. Vial 2, the colour developer, and Vial 3, the clarifying solution, are then poured onto the membrane. The test can produce four categories of result. A reactive result is indicated by the appearance of two circular dots, blue in colour on the membrane unit. A non-reactive result is indicated by one dot, the control dot, at the top of the membrane unit. An indeterminate result will demonstrate some blue colour, likely the shape of a hollow circle on the bottom of the membrane unit. An invalid result may produce a number of results, such as no control dot, lines or strange colouring to the device etc. The results are visualised in Figure 3.

**Figure 3.** INSTI™ HIV-1/HIV-2 Antibody Test results



### ***Trial results***

Throughout the RHIVA2 trial, intervention practices offered a total of 11,187 rapid tests, of which 4,978 (44.5%) were accepted. There were 14 reactive tests and 11 were confirmed HIV positive. Three were considered false reactives and were confirmed HIV-negative. Overall 43 patients were thought to be diagnosed as HIV-positive through both rapid and serology testing in intervention practices. Of these, 11 had been previously diagnosed, giving a total of 32 new diagnoses in intervention practices during the trial period, including three cases identified through antenatal screening. Control practices identified 21 cases of HIV through serology testing although seven had been previously diagnosed, leaving 14 new diagnoses, four of whom were diagnosed through antenatal screening.

The mean CD4 count in patients diagnosed during the trial period was significantly higher in intervention practices than control practices after pre-planned sensitivity analyses. The sensitivity analyses excluded patients diagnosed via antenatal screening and patients who had been previously diagnosed in the UK. There was a non-statistically significant trend towards diagnosis of HIV at an earlier stage of infection in the intervention group over the control group, the primary outcome of the trial. The secondary outcome of a greater rate of detection

of HIV was statistically significant in intervention practices where the rate of diagnosis was four times higher than in control practices.

The trial demonstrated the effectiveness of offering rapid HIV testing to new registrants in general practice in a borough with a high prevalence for HIV. Promoting opt-out rapid testing in general practice led to an increased and earlier detection of HIV once antenatal screening and prior diagnoses were excluded. Additionally, a high number of the cases diagnosed were in black Africans (62%) who are considered a high-risk and hard to reach group. The final trial paper was published in the *Lancet HIV* in 2015, stating: ‘Promotion of opt-out rapid testing in general practice led to increased rate of diagnosis, and might increase early detection, of HIV. We therefore recommend implementation of HIV screening in general practices in areas with high HIV prevalence.’ (Leber et al., 2015: p.1).

## Chapter 3: BACKGROUND TO METHODS

### 3.1 Philosophical and methodological approach

‘the initial moment of discovery in clinical or field bound situations (for those fortunate enough to have this experience) invariably evokes the sense that the whole project is turning to dust.’ (Fine and Deegan 1996: p.435 as quoted in Locke et al. 2008: p.910)

This study calls on different disciplinary traditions and modes of inquiry to produce a case study that elucidates why and how a particular intervention was deemed an effective mechanism for enacting national policy. By bringing a range of different disciplinary lenses to the RHIVA2 trial, I will describe contrasting versions of the ‘same’ event. These different perspectives have forced me to ask if the pragmatic RCT, and the evidence it produced, was a helpful way of interpreting and explaining RHIVA2. What does the ‘pragmatic randomised controlled trial’ account of events tell us, what is left out of this ‘telling’, and does it matter? Is the particular account provided by the trial one that moves toward the aims of producing better care and evidence for patients and the health care system? Are the different alternative accounts of this ‘same’ event complementary, non-coherent or otherwise? Exploring information drawn from different methods helps elucidate these questions through the provision of other knowable accounts or possible ‘evidence’ that both challenges and complements that produced by the trial.

My entry point into questions of epistemology has been through exploring methodology. I learned about different methods and the evidence they claim to produce without overt consideration of how these methods might be constructed and called upon to privilege particular modes of knowledge located in differing philosophical positions. Exploring methodology, versus methods, has meant learning more about how to think; what can be determined as ‘knowledge’ and ‘truth’ and claimed as the ‘real’. I will consider ways of understanding knowledge, truth and reality, and what the consequences may be for the mobilisation of methods, through a discussion of ontology, epistemology and paradigm.

### 3.2 Ontology, Epistemology, Paradigm

Within social science it is widely agreed that researchers approach their work and subjects through philosophical frames. The frames include perspectives on the nature of reality, truth, evidence and the best means for discovering and representing knowledge (Vasilachis de Gialdino, 2009). *Ontology* refers to the nature of being or reality, it is a branch of metaphysics concerned with existence (Law, 2004; Lincoln et al., 2011). Ontology and epistemology are related and form parts of paradigms. Ontology is often seen as the starting point for considering one's philosophical position. *Epistemology* is defined as the study of knowledge and justified beliefs; it considers how we know things to be true and how we come to these conclusions (Lincoln et al., 2011; Law, 2004; Hastrup, 2004). While ontology asks 'what is reality?', epistemology explores thought and knowledge with a concern for what constitutes our sense of justifiably knowable things. Methods are separate from but relate to epistemology as these are the means by which we come to know, and inform how we represent knowledge to publics (Denzin and Lincoln, 2011).

*Paradigms* include ontologies, epistemologies and methods and are a space where these different levels of consideration coalesce to produce social realities. Kuhn has defined a paradigm as 'the entire constellation of beliefs, values, techniques and so on shared by the members of a given community.' (Bryant, 1975: p.364 quoting Kuhn, 1962). A further clarification by George Ritzer helps us see how this might be enacted in science:

'It is the paradigm that defines what the scientist should and should not study, the paradigm that tells the scientist where and where not to look for the entities of concern to him; the paradigm tells the scientist what he can expect when he finds, and examines, the entities of concern to him.' (Ritzer 1975: p.5)

Methods are often discussed as sitting within particular paradigms, though paradigms tend to be described less in regards to methods. The RCT, for example, is commonly cited as a key evaluative tool for production of evidence within the evidence-based medicine paradigm, linked to a positivist philosophical position (Goldenberg, 2006). Much discussion has taken place regarding the possibility of mixing paradigms and their contents: views and manifestations of reality, knowledge and truth (Denzin and Lincoln, 2011; Hammersley, 2002).

Denzin and Lincoln draw a distinction between paradigms and perspectives and indicate that:

‘If paradigms are an overarching philosophical system denoting particular ontologies, epistemologies and methodologies, one cannot move easily from one to the other. Paradigms represent belief systems that attach the user to a particular worldview. Perspectives, in contrast, as less well developed systems, it can be easier to move between them’. (Denzin and Lincoln. 2011: p.5)

This point relates to debates in the research community around mixing methods and whether methods do in fact represent paradigms. This tension will be discussed at points throughout the thesis. First, I will briefly outline common positions on the philosophical spectrum.

### **3.3 Positions on the philosophical spectrum**

*Positivism* refers to a philosophical position where reality is knowable, external and enduring (Lincoln et al., 2011; Law, 2004). Within this paradigm the goal of science is to uncover the pre-existing reality of the world; knowledge is comprised of objective descriptions of this reality, making the truth empirical and proven by what we can observe and measure (Laudan, 1996; Lincoln et al., 2011). Positivist approaches often deal in facts and laws and typically rely on experimental and quantitative methods. Scientific truths are supported with rigorous empirical data that follow laws and can be objectively described (Law, 2004). The 1970s saw this paradigm subjected to wide critique, partially spawning the rise in alternative paradigms and methods (Denzin and Lincoln, 2011).

*Post-positivism* is used as an umbrella term encompassing some of the approaches challenging and critiquing (rather than just amending or refining) positivist assumptions. A number of positions fall under this umbrella including subjectivism, interpretivism and constructivism (Denzin and Lincoln, 2011). These approaches tend to suggest that individuals *construct* the world through their experiences, perceptions and reflections on phenomena (Law, 2004). This implies that there is not one knowable reality. Knowledge and truth are constructed in relative and subjective ways. Post-positivist approach gained ground in challenging positivism and centered the individual and their internal processes in the

understanding of social and cultural phenomena (Law, 2004; Denzin and Lincoln, 2011; Crotty, 1998). The range of approaches that embrace constructivism consider that human beings shape phenomena through perceptions, interpretations, and symbols of meaning (Law, 2004). They attribute these to the world around them and their experience of it. This means that knowledge and reality do not sit solely outside of individuals and that society is constructed through the interpreted meanings and understandings of human beings (Denzin and Lincoln, 2011; Law, 2004; Crotty, 1998).

*Interpretivists* do not believe the world can be objectively observed but that our relationship to phenomena is socially mediated. We attribute meanings to experiences and this relates to how we understand things to be true and accurate. Interpretivists focus on naturalistic methods and value narrative, reflection and context (Greenhalgh and Russell, 2010). Depending on one's orientation they will abstract or focus in on particular aspects of phenomena, demonstrating the role of the individual's relative perceptions in understanding reality (Crotty, 1998; Bastalich, 2015). *Social Constructivists* and *interpretivists* place meaning on language and interaction (Bastalich 2015). This view holds that 'all knowledge, and therefore all meaningful reality as such, is contingent upon human practices, being constructed in and out of interaction between human beings and their world, and developed and transmitted within an essentially social context.' (Crotty, 1998: p.42). Reality is relative, knowledge is subjective and hermeneutic; dialectical methods are often used to represent multiple truths and versions of reality (Lincoln et al, 2011; Law 2004).

The *critical perspective* highlights the ways in which knowledge and its production are infused with power relations that have political implications (Denzin and Lincoln, 2011). If the production of knowledge is reductive and selective and each research performance tries to organise information in a way that tells us something deemed important (from a particular perspective) then the political implications of knowledge production are more apparent (Hastrup, 2004). Methods can sit within a paradigm that positions the method as able to produce information qualified as knowable. However, in the process of ascertaining this knowledge there is a choice of what information to privilege and clarify, some information is inevitably left in the background, inexplicit and unaccounted for. What is important is how the ontological and epistemology approach can be contained or constrained in the enactment



of the method and the presentation of its results. Knowledge may be transformed into a neat and useful piece of evidence 'ready-to-use' in particular paradigms, which reflects but may not explicitly acknowledge its creation within a particular mode of knowledge and inquiry. As stated by Harstrup: 'knowledge, therefore is no simple 'object', because it bears all the marks of its institution, including a particular 'style of reasoning' that by itself becomes a standard of objectivity' (Hastrup 2004: p.456). This 'knowledge' may lend itself to creating evidence that better serves some populations, systems of belief and interpretations of the world than others, potentially contributing to the upholding of power amongst some groups and the repression of others.

### **3.4 Methodology: Between philosophies and methods**

Before moving onto a description of the methods used within this project, I will outline my approach to methodology. Here, methodology is defined as the set of assumptions, postulates and logics that inform the researcher's inquiry and choice of methods (Hesse-Biber, 2015). It can be seen as the design behind the choice of methods, or the construction of the 'road map' for the research (Crotty, 1998). Throughout the PhD, I have felt in need of guidance in working with the different forms of data combined here as well as the modes of inquiry used to obtain it. What became clear is that key 'sensitising concepts' have been integral in effectively thinking through the work presented here.

#### ***Sensitising concepts in moving towards methods***

'in studying any set of phenomena directly, we pass them before our eyes in the attempt to discover recurrent patterns and, if possible, to make out the entire configuration of events...These recurrent patterns gradually crystallise into concepts. Concepts result from the capacity of the mind to perceive the similarity of configurations perceived in succession. Concepts may be defined as transposable perceptual patterns to which we have given names. Imagination is often called into play to fit together pieces of configurations, to perceive with insight configurations of events which have not actually been present to the sensed.' (Waller 1934: p.3)

There are 6 key sensitising concepts that inform the methodological approach of this PhD. They include: *the experiment, the surplus, novelty, dwelling in doubt and tension, pragmatism* and *experience*. I will describe each below.

### *The experiment*

‘Experimental systems are extremely tricky and thick arrangements, as it were. One can see them as spaces of emergence – cultures of ‘access to an emergence’, in the words of Bachelard – as structures created by research in order to let things materialize that were not otherwise able to manifest themselves (to become thing-able) and therefore thinkable.’ (Rheinberger, 2015: p.168)

RHIVA2 was an experiment, a trial to see what would happen when we offered rapid testing to new registrants in general practice. It was, however, a highly bounded experiment with pre-determined outcome measures ordered, primary, secondary etcetera. I was drawn to the role as trial manager partially due to the drama of the experiment and its definitive claims. I wanted to see how this study was going to work out, if the findings would be statistically significant, if people would be diagnosed with HIV, and onwards. The generative nature of the trial device troubled and intrigued me. Steven Brown describes experiments as devices that ‘have the basic structure of creating a situation of “ordinary people being challenged” in order to facilitate some form of learning experience.’ (Brown 2012: p.64). He refers to experiments as social technologies that identify and organise individuals in a way that tries to isolate particular experiences, can be repeated and are ‘open for coding, such that what may be learnt from the experience is rarely as straightforward as those who articulate the challenges (i.e. the experimenters) may intend or those who enact the challenges (i.e. the participants) experience at the time.’ (Brown 2012: p.64). Brown quotes philosopher Isabelle Stengers on experiments to also describe them as ‘methods of inventing or creating new forms in which the world is deemed able to “speak” ’ (Brown 2012: p.64). This, Stengers claims, requires a ‘complex game of construction and mobilization, where a network of interests and stakes are made to pass through the experimental setting’ (Brown 2012: p.64).

A process of construction and mobilisation is, in many senses, what I thought my job was as trial manager, defining the bounds of the experiment, imparting knowledge, and inspiring actions to make the trial productive. While these authors are discussing the psychological experiment, broadening thinking about the experimental method beyond how it is described in the pragmatic trial appeals to me (this will also be taken up further in Part 3). It is with this view that the experience of the trial opens up and where I felt I could engage with some of the ‘surplus’, some of what the trial, the experiment, produced but was not made explicit in the trial design. In considering experimentality in this way, I am approaching the trial as a broad experiment, as a device that probes and creates with multiple effects. Annemarie Mol, in her work *The Body Multiple*, encourages us to consider methods as interferences and as mediators versus tools that uncover the truth of something. With this view, she encourages us to consider not only ‘is this intervention effective?’ but also ‘what effects does it have?’ (Mol 2002: p.183).

### *The surplus*

Attending to the effects of the trial beyond those intended requires paying attention to the ‘surplus’ (Hastrup, 2004). In her article ‘*Getting it right: Knowledge and evidence in anthropology*’, Kirsten Hastrup discusses the nature of evidence in a ‘post-positivist era’ (2004). She argues that it is not supportable to consider evidence as external to the context of a moment or relation:

‘Knowing is a matter of perspective; there is no knowledge without someone who knows in a particular way. Knowledge, therefore, is a social phenomenon rather than simply a substance. To maintain scholarly authority one must be able to account for the particular mode of interest that gives direction and shape to knowledge’ (Hastrup 2004: p.146).

She goes on to discuss ‘anthropological knowledge’ (Hastrup 2004: p.458) as emergent, without an ontological status. She points out, quoting Diley, how we tend to treat context and situation as objects that can be added and removed from scenarios. She continues, quoting Daston, on how facts are transformed into a particular kind of knowledge - evidence - and how as a result they lose their status as facts since persuasion has been attached (Hastrup 2004: p.158). Regarding the ethnographic method, she asserts that:

‘fieldwork discloses the fact that there is always a historical surplus of events, actions and thoughts that may linger without necessarily contributing to the larger order as perceived, but providing possible sites of resistance or sources for new historical turns’ (Hastrup 2004: p.464).

What she describes here resonated deeply with what I feel this PhD moves towards, the surplus from my initial inquiry and the surplus of the trial, the data emerging from RHIVA2 that never gained status as data, evidence, or was even recognised as information by the trial logic. When the trial is explored through a different set of epistemological assumptions and methods, new ways of considering the impact of the trial, with implications for the pragmatic trial, may be demonstrated and spaces opened up that seemed closed down or non-existent when thinking with the trial logic alone.

Another dimension of Hastrup’s considerations also resonates strongly with my process throughout this study. She discusses the role of the ethnographer as a form of ‘double agent’, acting as a researcher on the one hand and in the role required by the environment on the other. Within this, she discusses the importance of ‘living the character’ and essentially buying into the assumptions and the logics in the setting under study. In my case, the ‘buying in’ was easily done in my role as trial manager and in living through what often felt like the ‘dysfunction’ of the trial. The tension between my questions (described in Chapter 2: Background) and the trial is what initially inspired this PhD. Hastrup describes this role:

‘The point is to get away from the dualism of thought and action in recognition of the fact that knowledge is practical, and that theoretical or abstract knowledge is a special case of this (Jenkins, 1994:442). This is a correlate to claiming there is no opposition between practical (material) experience and its theoretical (linguistic) rendering: they are deeply implicated in one another.’ (Hastrup 2004: p.466)

The process of acting and thinking the research means it can be difficult to untangle where methods end and analysis begins.

### *Novelty and ‘being a beginner’*

I have come to consider my ‘beginner’ status as a key aspect of the work presented here. RHIVA2 was my first experience of a trial and a population screening intervention. I was

also new to the UK and had very little work experience in London or the health care system. In *'The Structure of Scientific Revolutions'* Thomas Kuhn describes 'the normal science' (1962), where work is undertaken in an established paradigm or explanatory framework which the scientific community acknowledges as foundational. As a beginner in this field, I was unaware of the 'normal science' of trials. This is relevant in that I was often unsure of where and how to attune my focus, questions and observations. While experience and knowledge may allow us to see depth and nuance, I feel that my attention to particular dimensions of the trial was a result of not knowing what was 'normal' or of having entrenched 'habits' or tacit understandings of how things worked. This naïvety, while sometimes difficult, meant I often could not filter out what was or was not important and may have contributed to some of the most productive research tensions, which inspired the approach to methods here. One common feeling was that of doubt, sometimes in myself, in our interventions potential, in the positivist approach, and onwards.

### *Dwelling in doubt and tension*

'This feeling of unsettledness causes us to start and sustain our inquiry. Doubt is an experiential signal that there is a need to reconsider and revise our ways of understanding' (Anderson 2005, Hildebrand 1996)' (Locke et al. 2008: p.910)

My position as a beginner relates to a passage encountered in the article *'Making Doubt Generative: Rethinking the Role of Doubt in the Research Process'* by Locke et al., a text which highlights another important dimension of my methodological process (2008). Here, the authors discuss the generative potential of doubt to improve theorising. In valorising abductive reasoning, as opposed to induction or deduction, space is opened for speculation, conjectures, and assessments of plausibility, which they articulate as a part of the abductive process, described in the quote below. This sits in contrast to hard facts and pre-set truths, emphasising the emergent and the 'unanticipated and unexpected', with an explicit role for emotion (Locke et al. 2008: p.908). In describing the pragmatic philosopher Peirce's description of doubt they write:

'Pierce indicates (CP 5:394) that he uses 'doubt' 'to designate the starting of any question, no matter how small or great', and 'belief' to designate the resolution of it. "Beliefs, as doubts which have been resolved, are the habits of interpretation and action ready for use, and in use, in our transactions with the world. As habitual and

received, they represent continuance and are the steady state of our everyday understanding, living, and working: we engage the world with habit-laden ways of apprehending that are developed in the course of our lives. Doubts, on the other hand, arising when that continuance is interrupted, represent a potential inadequacy in these habitual ways of understanding and acting. Doubt is the ‘privation’ of habits. As “privation”, doubt represents a “condition of erratic activity” (CP 5:417); its irritation excites the “action of thought” that only ceases when “belief is attained” (CP 5:394) when the questioning is resolved.’ (Locke et al. 2008: p.908).

In retrospect, and without any intended negative association, I doubted the research process we were engaged in throughout the trial. While I did not doubt that the trial was being enacted ‘correctly’, I doubted its ability to adequately describe events and account for the ‘scientific and the social’ as claimed by the pragmatic trial design. The more open process of abduction is an appealing approach to methods and the project as a way of exploring this broad phenomenon.

### *Pragmatism vs. pragmatism*

‘The principle of pragmatism, according to James, was first enunciated by C.S. Pierce, who maintained that, in order to attain clearness in our thoughts of an object, we need only consider what conceivable effects of a practical kind the object may involve. James, in elucidation, says that the function of philosophy is to find out what difference it makes to you or me if this or that world-formula is true. In this way theories become instruments, not answers.’ (Russell, 1996: p.727)

When beginning the trial, I thought the pragmatic key of the trial related to demonstrating the overall utility of an intervention in context. I believe this to be a generally accurate and widespread understanding of what the pragmatic trial refers to. As I engaged in PhD-level inquiry, I started to learn about pragmatism as a philosophical stance. I wondered how the two forms of pragmatism relevant to my work were related. In considering the ‘pragmatic’ trial and in what sense it aims to be pragmatic, I was struck by a line in Bertrand Russell’s lengthy *History of Western Philosophy*. In describing the work of James, a seminal pragmatist, he writes: ‘our obligation to seek truth is part of our general obligation to do what pays... We cannot reject any hypothesis if consequences useful to life flow from it’ (Russell, 1996: p.728). As the pragmatic trial aims to evaluate interventions in their context of use, in the ‘real world’, it could be said to align with this thinking – does it pay to intervene in this

way? Are the consequences useful? However, which consequences we attend to, and which productive experiences we evaluate affects the question. Despite this resonance, additional dimensions of pragmatist philosophy seemed in sharp contrast to the logic of the pragmatic trial. These may include, the emergent nature of reality, reality as non-static, and emphasis on abductive reasoning. As will be discussed later, in Part 3 of the thesis, pragmatic trials retain enough of the RCT logic – that reality is positioned as external, enduring and discoverable - and much of the trial apparatus enacts these assumptions.

### *Experience*

If a pragmatist philosophy emphasises experiences - events as constitutive of consciousness and beings as ‘the experiences we have’ (DeForge and Shaw, 2012: p.88) - applied to this project, it asks what forms of experience are produced by an experiment such as a pragmatic trial of a population screening programme. If ‘truth as practical consequences’, is a pragmatist approach to the real, what are the ‘real world’ consequences of a population screening programme for HIV rolled out as a pragmatic randomised controlled trial?

The emphasis on ‘experience’, as the generative goal of an experiment, as comprising ‘the surplus’, as the ‘interferences’ of methods and, in pragmatism, as constitutive of practical consequences, beings and the real, demonstrates how experience is an object of study in this research. In exploring experiences related to the population screening intervention for HIV and the pragmatic trial, I am not seeking to reveal the whole ‘truth’ of the trial or of the impact of population screening programmes. At best, I aim to explore some of the consequences or experiences produced by the intervention and their impact on general practices, staff and patients. This approach resonates with the concepts outlined above and a loosely pragmatist approach to knowledge, where ‘pragmatism would not seek to identify any real causes as such, the methodological guidance it provides simply leads us to focus on different things – in this case, on contextualized experiences that inform the consequences of inquiry’ (DeForge and Shaw, 2011: p.92).

## Chapter 4: METHODS

‘Studying methods empirically, then, generates another understanding of what they are. No formal guarantees, but specific mediators, interferences. The question to now ask is how they mediate and interfere.’ (Mol 2002: p.155)

While using multiple methods has been a challenge, it has also provided some of the more interesting insights and findings of the project, which should become apparent throughout the thesis. Having already described my sensitising concepts and discussed the philosophical underpinnings of methods, I will now describe the methods used to collect the empirical data analysed in this PhD. It is my hope that the accounts produced through these methods will allow for a ‘thick’ description of the experience of a rapid HIV testing trial in general practice (Geertz, 1973).

### 4.1 Case study

‘A case carries knowledge, not in the form of firm rules or statistically significant regularities, but in the form of a story about an occurrence that, even though it may have happened just once, is still telling, indicative, suggestive. It condenses experience that is not general, but inspirational. As cases are idiosyncratic, those who seek inspiration from them still have to think for themselves. They have to adopt the lessons learned to the situation in which they find themselves. Cases, then, do not transport knowledge smoothly. It requires work to draw on them. The implications here of a case that occurred elsewhere, have to be carefully thought through and tinkered with. Such tinkering may serve highly varied goals.’ (Mol, 2015: p.2)

The main research method used in this PhD is case study. Principally, this is a case study of a rapid HIV testing trial in general practice. However, case study is also used in other ways throughout the PhD, for example in Part 2, where four case studies of general practices with varying performances in innovation implementation are developed and in Part 3, where patient cases are presented, as a result, case study is understood as an overarching method for the study of RHIVA2 but ‘cases’ from the broader case study are used to illustrate findings.



Case study allows for ‘in depth, multi-faceted explorations of complex issues in their real life settings’ (Stake 1978: p.5). The RHIVA2 trial demonstrated the overall efficacy of rapid testing in achieving key indicators such as the early detection of HIV. However, understanding the complexity of practice level characteristics such as patient demographics, practice size, culture and attitudes towards testing, while including trial performance data, demands a methodology that accounts for complexity and a diversity of data types. Stake discusses case study as strongest ‘when the aims are understanding, extension of experience, and increase in conviction’ (Stake 1978: p.5). He describes case study as:

‘descriptions that are complex, holistic and involving a myriad of not highly isolated variables; data that are likely to be gathered at least partly by personalistic observation; and a writing style that is informal, perhaps narrative, possibly with verbatim quotation, illustration and even illusion and metaphor.’ (Stake, 1978: p.7)

While case studies may include statistics and quantitative data, what is central to the method is the ability to draw on experiential knowledge and multiple data sources to develop a deeper understanding of complex human phenomena (Stake, 1978; Mol, 2015).

In discussing what knowledge is best gained from case study method, Stake contrasts tacit with propositional knowledge. He describes propositional knowledge as mostly gained through observations of objects and events, while tacit knowledge also includes the knowledge gained from one’s experiences of these events and their ruminations about them (Stake, 1978). The RHIVA2 case study allows for the inclusion of both tacit and propositional knowledge about HIV testing in primary care, as the work presented here combines my lived experience of the trial, testimonies of the experience of patients and providers, ethnographic data and also quantitative data in the form of results from RHIVA2.

Undertaking a case study can be broken down into five general phases of work. Of primary importance is defining the case. This requires articulating the boundary of the case which includes the population or site, the time period, geographical area of interest and the types of evidence needed. This may include the inclusion of theory. Second is selecting the case. Case study sampling might include deviant or atypical sampling or some other selection method; case studies are not normally chosen at random (Flyvberg, 2006). Data collection is the third step; this will likely include various sources of data, which may range across the

qualitative and quantitative spectrum. While researchers are cautioned about over-collection there should be multiple sources of data to add validity and the potential for triangulation (Crowe et al., 2011). Analysing and interpreting the data can be a long and immersive process. It is suggested that for collective case studies, cases are looked at independently of each other primarily and analysed together only after in-depth engagement and interpretation of each individual case. Commonly used in analysis is the framework approach articulated by Spencer and Ritchie (Spencer and Ritchie, 2003). The role of theory in the case study is quite important at this stage, as this may be the point where theory testing or development is articulated (Crowe et al., 2011). Finally comes reporting the findings. Here is where a cohesive narrative and instructive example is offered to the target audience. Readers should have enough information about the case and the context to be able to evaluate the data collection and sampling methods but also be offered some overarching analysis which allows for greater overall insights into phenomena (Crowe et al., 2011). The ethical considerations of case study are dependent upon which methodologies and data collection practices are employed in building the case, different cases will have unique ethical considerations which may include anonymising data, gaining agreements and permissions, managing the role of the research sponsor, and negotiating the use of data and the extent of publication with participants, amongst other considerations (Simons, 1989).

### *The N of 1*

A commonly cited limitation of case studies is a lack of generalisability. It is argued that case studies are informative about that which they directly investigate but that these findings can rarely be extended beyond the case to larger populations. When compared to experimental studies that aim to produce widely generalisable results, it does appear that case studies are small in their applicable scope. However, Stake proposes that what causes case studies to be ungeneralisable in some senses (discussion of the specifics, the subjective and the experiential) is paradoxically what allows them to be generalisable (Stake, 1978). He argues that they are 'naturalistically generalisable' due to their epistemological coherence with the reader's experience (Stake, 1978).

‘naturalistic generalisation, arrived at by recognising similarities of objects and issues in and out of context and by sending the natural covariations of happenings. To generalise this way is to be both intuitive and empirical, and not idiotic.’ (Stake, 1978: p. 8)

Investigating the ways national HIV testing policy was implemented in one borough, with emphasis on intervention adoption and overall performance, may be instructive to other boroughs which share similar patterns of HIV epidemiology and qualify for the BHIVA and NICE guidance. The shared health system, policy guidance, likeness of epidemiological factors and location within the same city may mean that there is greater likelihood for effective generalisability. On a larger scale, the explicit inclusion of theoretical approaches such as the diffusion of innovations model by Greenhalgh et al. (see Part 2) aims to extend the utility of the findings through the suggested theoretical benefit of insight generation across domains.

In her article ‘*In praise of small N, and of N=1 in particular*’, Lindsay Prior outlines some of the strengths and benefits of studies that use a single exemplar. Listing five key factors she describes how such studies can be seen as a ‘natural kind’, where a single case can ‘contain and exemplify the essential characteristics of its kind and a study of one is, in so many ways, a study of all’, allowing us to be informed ‘about the essential features of a much larger category’ (Prior, 2016: p.115-116). N=1 studies can also ‘focus entirely on the specificity and singularity of the case because its unrepeatable nature is of critical importance (Prior, 2016: p.116), such as the disastrous space shuttle Challenger launch, which crashed and therefore prompted intense investigation so that any like error could be avoided (Prior, 2016). Such studies may also:

‘explore the multiple intricacies and interconnections that arise both within the case and between the case and the world’ and finally ‘the single, isolated ‘1’ can, if required, be used a disconfirming instance of some generalisation or other, i.e. as one of Karl Popper’s black swans’ (Prior, 2016: p.116).

Flyvberg also discusses how the instructive value and ‘force of’ example is underestimated in research (Flyvberg, 2006). He goes as far to say that generalisation is overvalued as a source of scientific development and quoting Beveridge asserts that ‘more discoveries have come from intense observations that statistics applied to groups’ (Flyvberg, 2006: p.35). He also points out the importance of case studies’ ability to falsify commonly held beliefs through the

illustrative example of the black swan. If ‘all swans are white’, the discovery of a black swan invalidates a generally held belief, also indicating that ‘what appears to be ‘white’ upon closer examination often turns out to be ‘black’ (Flyvberg, 2006).

The BioMed Central review of case study methodology indicates that other limitations to case study method might include lack of scientific rigour, subjectivity and over-collection of data (Crowe et al., 2011). They indicate methods of mitigating these limitations, which include an emphasis on transparency. This can be achieved through ‘describing in detail the steps involved in case selection, data collection, the reasons for the particular methods chosen, and the researcher’s background and level of involvement’ (Crowe et al. 2011: p.100), including clarity about how the researcher influenced and has been influenced by the study. My role in the RHIVA2 trial was trial manager, which meant regular in-depth engagement with the practices and the research team. I had a vested role in the study and a specific relationship with the practices but also a front row seat and active experience of trying to implement HIV testing policy. Here we see the strength and problem of experiential data collection as the depth of tacit knowledge could not have been achieved without this role, however a set role within the process invalidates any claim to neutrality.

### *Telling stories*

Many of the methods used to answer the main research question and sub-questions (listed in Table 1) are aligned with research that ‘emphasizes episodes of nuance, the sequentiality of happenings in context, the wholeness of the individual’ (Stake, 1995: p.1). In other words, they acknowledge the subjective nature of human experience and reality and embrace these particularities, versus placing emphasis on causality and representative sampling. However, the scientific objective of gaining insight remains. The lack of objectivity forms a part of the methodological approach, emphasising that the thoughts and impressions of the researcher are an important source of data. Qualitative approaches acknowledge that knowledge is both internally and externally derived (Gomm et al., 2000). As pointed out by Richard Winter in his creative discussion of case study in *‘Fictional-critical writing: an approach to case study research by practitioners’*: ‘we do not “store” experience as data, like a computer; we “story”

it- in anecdotes, jokes, dreams, ambitions, and gossip.’ (Winter,1986: p.176). This articulation of the ways we collect, reflect upon and share our experiences demonstrates the importance of qualitative data and the usefulness of the case study methodology in developing understanding.

Much of the qualitative work, which comprises a part of my case studies, manifests itself in the way described above, as nurses, health care assistants, patients and GPs reflecting upon their experiences and sharing anecdotes. At once, one learns about their layered interactions with rapid HIV tests, how it made them feel, the conflicts it encapsulates, the interactions with patients, the arguments about how to roll it out within the surgery, and onwards. It is only by including these ‘stories’ as data that we are able to see what information they store in regard to rapid HIV testing in primary care and what the innovation in action actually presents as to those enacting it. The stories help to complete the larger picture of the trial, ripe with various players, contexts and dynamics that come together to determine the theoretical possibilities around a policy and intervention in action.

Finally, the use of case study as an appropriate method, despite its strengths and limitations, is relative to the fit to the research question. Case study has the ability to sit on a continuum between the objectivist and subjectivist approach based on the data utilised. The trial demonstrated the efficacy of testing but does not capture the level of implementation or the challenges faced in rolling out the intervention. To answer the central questions of the research project, engagement with the messy work of policy in practice is required, and this links well with the case study method for the reasons articulated in the above discussion. Overall, the wider project demands an interpretivist approach, employing qualitative methodologies to paint a rich picture of a policy from articulation to action and of the role of an experimental trial within that evolution.

The broad case presented here is comprised of three sub-studies with emphasis on the synthesis of the findings from each. The sub-studies take place at the policy, provider and patient level (Parts 1,2,3 of the thesis) and aim to trace the RHIVA2 trial and its interventions from conception in policy through to enactment on patients.

As mentioned above, data sources will be discussed separately in Parts 1, 2 and 3 of the thesis, preceding the findings chapters presented in each. This approach was chosen to improve coherence of the thesis and is described in the introduction.

## **4.2 Autoethnography**

While case study forms the broad method used in the PhD, another overarching method is autoethnography. Carolyn Ellis and colleagues describe autoethnography as a combination of autobiography and ethnography where personal experiences are described and systematically analysed in order to better understand culture (2010). She understands the turn to autoethnographic methods as a response to the critiques of canonical ideas about research conduct and the growing field of cultural studies and its critique of the ‘view from nowhere’:

‘Autoethnographers recognize the innumerable ways personal experience influences the research process. For instance, a researcher decides who, what, when, where and how to research, decisions necessarily tied to institutional requirements (e.g. Institutional Review Boards), resources (funding), and personal circumstances (e.g. a researcher studying cancer because of personal experience with cancer)... Consequently, autoethnography is one of the approaches that acknowledges and accommodates subjectivity, emotionality, and the researcher’s influence on research, rather than hiding from these matters or assuming they don’t exist.’ (Ellis et al., 2010: p.2)

Personal experience is reflected upon and written up. The experiences reflected upon were not assembled as part of a research project, but constitute elements of the author’s life. As a result, this process is usually done in hindsight and intentionally infuses emotion, personal detail and factual information about the events or phenomena under consideration. This process is described in the quotes below:

‘When writing an autobiography, an author retroactively and selectively writes about past experiences. Usually, the author does not live through these experiences solely to make them part of a published document; rather, these experiences are assembled using hindsight.’ (Ellis et al., 2010: p.2)

Leon Anderson aims to articulate different forms of autoethnography in his article ‘Analytic autoethnography’ (2006). He contrasts the analytic approach to autoethnography to the

‘evocative’ autoethnography proposed by Ellis et al., which he describes as becoming popularised alongside the post-modern critique of anthropology. Analytic autoethnography is suggested as an alternative to ‘evocative’ autoethnography in that it aims to be ‘consistent with qualitative inquiry rooted in traditional symbolic interactionism’ (Anderson, 2006: p.374). Anderson outlines analytic autoethnography’s five key features, including, 1) the researcher is ‘complete member researcher (CMR), (2) analytic reflexivity, (3) narrative visibility of the researcher’s self, (4) dialogue with informants beyond the self, and (5) commitment to theoretical analysis.’ (Anderson, 2006: p.378). In relation to Anderson’s criteria, my work fulfils the criteria of analytic autoethnography and is aligned with this description to a greater degree than ‘evocative autoethnography’. I will briefly describe how my work fulfils the criteria.

Anderson stipulates that analytic autoethnography requires that the researcher be a ‘complete research member’, linking to the experiential knowledge of the phenomena being explored. As the only full-time staff member of the RHIVA2 research team I spent each day implementing and managing the trial. Progressing from a part-time research assistant to the full-time trial manager I had a close relationship to many of the trial actors and a close view of what was taking place day to day. As described in the Introduction and Background, my regular activities included all that made the trial ‘work’ along with fulfilling many of the bureaucratic activities associated with working in research. Much of the reflection informing this PhD pulls on this experience.

For a time, the autoethnographic approach was unintended in that I had no aim of conducting the research presented here. At some point I became interested in the process and began collecting more extensive field notes. As a plan for a proposed PhD project developed, the ethnographic work become more intentional. Hundreds of hours of ethnography were undertaken. My prior experience working on the trial also impacted my perceptions and interactions throughout the PhD research. When interviewing providers, we had pre-existing relationships: I had a good knowledge of their practices and in some cases their colleagues; I had observed many of them performing tests; I had provided the training on the use of rapid tests, taught quality assurance procedures, trouble shot arising issues and installed templates

on EMIS, amongst other activities. This experience qualifies me as a ‘complete research member’ in the view of Anderson’s criteria for analytic autoethnography.

‘It entails self-conscious introspection guided by a desire to better understand both self and others through examining one’s actions and perceptions in reference to and dialogue with those of others.’ (Anderson 2006: p.382)

Throughout the trial and the PhD, I have engaged in reflexivity. This has been hopefully reflected in the presentation of the findings herein. I have aimed to be a reflexive researcher in regards to the phenomena under study but also throughout the process of the research itself. The engagement with theory and the analytic process described throughout relates to this criterion.

‘A central feature of autoethnography is that the researcher is a highly visible social actor within the written text. The researcher’s own feelings and experiences are incorporated into the story and considered as vital data for understanding the social world being observed.’ (Anderson 2006: p.384)

I have included my reflexive narrative in an obvious way by using the first person tense and actively including emotion and subjectivity as an integral aspect of my research philosophy, process, analysis and presented conclusions. I have not claimed neutrality nor a view ‘from nowhere’. Aligning with my analytical themes of ‘doubt’, ‘the surplus’ and ‘experience’ (See Chapter 3) - all of which rely on a situated, thinking, feeling researcher - I have been explicit about my desire to consider subjectivity as essential to my research process.

‘The ethnographic imperative calls for dialogue with ‘data’ and ‘others’. (Anderson 2006: p.386)

‘Unlike evocative autoethnography, which seeks narrative fidelity only to the researcher’s subjective experience, analytic autoethnography is grounded in self-experience but reaches beyond it as well.’ (Anderson 2006: p.386)

A number of formal qualitative interviews have taken place with providers, patients and policy makers (N=42) and these interviews form a key data source for the work presented here. Throughout the period of the trial and the PhD I have also engaged with various researchers, policy makers and others with a relationship to the trial or to HIV testing more broadly.



Anderson describes how the intention of analytic autoethnography is to contribute to large understandings of social phenomena through improved theorising. He is sure to articulate that this is not to produce ‘unbeatable conclusions’ (Anderson 2006: p.388), but to contribute to a ‘spiraling refinement, elaboration, extension and revision of theoretical understanding’ (Anderson 2006: p.388). A number of different theoretical perspectives have been employed throughout the PhD to account for the findings presented here. In some cases, these theories have been extended - such as in Part 2, the organisational study - based on the findings presented. In other areas the theories provide frames for which to make both theoretical and applied contributions (Part 2, Part 3).

Case study and autoethnography form the overarching methods used in the thesis. Each sub-study, comprising the larger case study, draws additionally on different methods to construct the findings. Below, I will describe discourse analysis and qualitative interviews before concluding with a description of process evaluation.

#### **4.3 Discourse analysis: Parker’s model as adapted by Shaw**

Discourse analysis is a broad and varied analytic method with substantial origins in linguistics and popularised in sociology and the political sciences by Foucault (Fairclough, 2003). Discourse can be broadly considered as:

‘a level of component of language use, related to but distinct from grammar. It can be oral or written and can be approached in textual or sociocultural and social-interaction terms. And it can be brief like a greeting and thus smaller than a single sentence or lengthy like a novel or narration of personal experience and thus larger than a sentence and constructed out of sentences or sentence-like utterances.’ (Sherzer, 1987: p. 296)

Foucault has acknowledged his role in the development of the term discourse, adding:

‘I believe I have in fact added to its meanings: treating it sometimes as the general domain of all statements, sometimes as an individualizable group of statements, and sometimes as a regulated practice that accounts for a number of statements.’ (Foucault as quoted by Fairclough, 2003: p.123)

Shiffrin et al., in their introductory text to discourse analysis, describe the method in three ways, as the study of language use, the study of linguistic structure ‘beyond the sentence’ and

as the study of ‘social practices and ideological assumptions associated with language or communication’ (Shriffin et al., 2009: p2). The third approach, the sociocultural approach, appears most relevant to the work undertaken here as it places emphasis on the ‘general characteristics of speech/ discourse communities’ (Shriffin et al. 2009: p.2). This critical approach questions the position of discourse subjects and the ways discourses impact upon and maintain power. Sara Shaw, whose adaptation of Parker’s framework is drawn upon in this chapter, describes discourses analysis as:

‘the study of social life, understood through analysis of language in its widest sense (including face-to-face talk, non-verbal interaction, images, symbols and documents). It offers ways of investigating meaning, whether in conversation or in culture.’ (Shaw and Bailey, 2009: p.413)

Shaw and Bailey outline four approaches to discourse analysis. Firstly, a micro level analysis would include a close look at language in use and draw from conversation analysis techniques (Shaw and Bailey, 2009). Analysis in this case may explore discourse from moment to moment between two participants with an emphasis on uncovering ‘cultural and communicative patterns’ (Shaw and Bailey, 2009). Meso-level analysis places focus on broader contexts yet may include face-to-face analysis (Shaw and Bailey, 2009). This includes social and cultural norms. Macro studies look at wider society and its ideologies and how language plays a role in shaping social possibilities (Shaw and Bailey, 2009). This can include knowledge construction and its link to what it is possible to imagine and therefore enact. Finally, discursive analysis tends to be more critical, looking at power and how groups use language to gain, maintain and exert control (Shaw and Bailey, 2009). Shaw and Bailey discuss how different levels of discourse analysis are often combined in studies utilising this method.

I aim to explore the key discourses operating in my sample of interviews and the policy document, with the intention to uncover how these discourses contributed to and justified the recommendation of offering new patients in general practices in areas endemic with HIV an HIV test at the point of registration. In analysing both the policy documents and the interviews, I draw on Parker’s method of discourse analysis, as adapted by Shaw for health policy, and provide a meso-level analysis with some discussion of the macro elements and discursive implications. Parker’s approach to discourse analysis as well as Shaw’s adaptation are summarised in Table 2 and Table 3.

**Table 2.** Parker’s method of Discourse Analysis (Hill, 2012; Parker, 1992; Shaw, 2010)

<b>Parker’s 20 steps in discourse analysis</b>	
<b>1.</b>	Convert the text into written form
<b>2.</b>	‘Free associate’ the text
<b>3.</b>	Systematically itemise ‘objects’ that appear in the text
<b>4.</b>	Consider these now, to be the ‘objects’ of your study
<b>5.</b>	Systematically itemise the ‘subjects’ who appear in the text
<b>6.</b>	Construct the rights and responsibilities of the most important subject in the set that describes the network of relationships that position this subject with others.
<b>7.</b>	Map the versions of the social world that co-exist in the text.
<b>8.</b>	Speculate upon the counter-argument of the addressor and their treatment of addressees who objected to the addressor’s stance and who took the contrast stance.
<b>9.</b>	Identify contrasts between ‘ways of speaking.’
<b>10.</b>	Identify where these ‘ways of speaking’ overlap (and also where they remain apart?)
<b>11.</b>	Consider other texts in the same domain and how the different ways of speaking address different audiences, or the same audience in different contexts.
<b>12.</b>	Choose appropriate terminology to label the emergent discourses you have identified.
<b>13.</b>	Engage in a study of where and when these discourses developed.
<b>14.</b>	Describe how the discourses have operated to so naturalise the things they referred to that they have become ‘taken for granted’ and that it appears perverse and nonsensical to question them.
<b>15.</b>	Examine the role of the discourses in reproducing and preserving these institutions.
<b>16.</b>	Examine which discourses subvert the above.
<b>17.</b>	Who would be advantage, disadvantaged, supported and threatened by each of these alternative discourses?
<b>18.</b>	Who would choose to support and who would choose to discredit these alternative ‘ways of speaking.’
<b>19.</b>	How does each discourse entail other discourses that enjoy power?
<b>20.</b>	How do these reproduce or challenge mindsets as to what can change and what is possible for the future?

**Table 3.** Shaw’s adaptation of Parker’s method of discourse analysis (Shaw and Bailey, 2009; Shaw, 2010)

<b>Shaw’s adaptation of Parker’s method of discourse analysis</b>	
1.	Discourse is realised in texts
2.	A discourse is historically located
3.	A discourse is about objects
4.	A discourse contains subjects
5.	A discourse is coherent system of meanings
6.	A discourse refers to other discourses
7.	A discourse reflects on its own way of speaking
8.	Discourses support institutions
9.	Discourses reproduce power relations
10.	Discourses have ideological effects

In Part 1, where this method is used, I suggest how discourses contribute to the policy making landscape in the field of HIV in the UK and in particular to the promotion of universal HIV testing for new registrants in primary care.

#### **4.4 Qualitative interviews**

Conducting interviews is a widely used approach in qualitative methodology. This PhD uses qualitative interview data as the main data source and interviews were undertaken with three groups: policy stakeholders, providers of rapid HIV testing and patients who tested HIV-positive with the first test being the rapid HIV test. While the PhD also calls upon ‘naturally occurring’ materials (Peräkylä and Ruusuvoori, 2011), such as ethnographic data and policy documents, these interviews allow for the exploration of subjective experiences, attitudes, and impressions about HIV testing in general practice (Peräkylä and Ruusuvoori, 2011). As I was not able to directly observe the offer of rapid HIV testing to newly registering patients, the construction of HIV testing policy, or the diagnostic experiences of patients, interviews

allow for the recounting of these key events by overcoming these temporal, spatial and access issues. These benefits are understood as a driving rationale for the use of qualitative interviews in health research (Peräkylä and Ruusuvoori, 2011).

A total of 42 qualitative interviews were undertaken in the PhD. The details of these are described more fully in Parts 1, 2, and 3, in the description of data sources. The qualitative research has aimed to be dialogically engaged with data from other sources throughout the PhD, versus presented alongside other findings (Pope and Mays, 2009). In their methodological review paper for the National Center for Research Methods entitled: *How many interviews is enough?*, Sarah Elsie Baker and Rosalind Edwards explore this question in regards to qualitative research by collecting a number of expert views on the subject (2012). The overarching response to the question was: it depends and relates to the setting, questions and context of the research (Baker and Edwards, 2012). Data saturation was not reached but the number of interviews it was possible to undertake was constrained by eligibility and agreement to participate. For example, only 11 patients were identified as HIV-positive through rapid testing, making for only 11 eligible patient interviews, of which 5 agreed to an interview.

#### **4.5 Process evaluation**

In Part 2 of the thesis, which explores the organisational level study, process evaluation is the central method used to explore the variation in uptake of rapid testing amongst RHIVA2 intervention practices. Process evaluation emerged as a method able to incorporate multiple forms of data and explore the dose, reach and fidelity (these concepts are further explained later in the chapter) of the rapid HIV testing intervention (Moore et al., 2013). Process evaluation has been suggested as a method to be applied alongside randomised controlled trials, particularly those analysing clusters (such as RHIVA2), as a way of better understanding the mechanisms of interventions and determining whether or not the intervention itself is ‘faulty’ or if the process of implementation hindered the impact of the intervention (Oakley et al., 2006). By taking into account dimensions that may affect the outcomes of trials, process evaluations can help interpret outcomes and provide insights that might make the mechanisms of interventions more understandable, and potentially

generalisable (Oakley et al., 2006; Moore et al., 2013). Pragmatic trials, such as RHIVA2, are said to benefit from such studies in the feasibility and conduct phases of the trial as a way of accounting for ‘external’ and contextual factors that impact upon the intervention.

The literature on process evaluation and the calls for its greater inclusion in experimental approaches to research comes alongside the increased attention to, and interrogation of, complex interventions and their measurement which some have termed the ‘turn to the complex’ (Mowles, 2014).

‘The argument that process evaluation is most useful in cluster trials, and where the intervention is non-standardised, also applies to many ‘pragmatic’ clinical RCTs, as does the idea that process evaluation in feasibility studies is crucial to developing appropriate and effective interventions.’ (Oakley et al., 2006: p.415)

Key concepts related to the outcomes of process evaluations are implementation, mechanisms of impact and context. The implementation process may aim to measure the fidelity, dose and reach of interventions. Fidelity refers to how faithful the implementation of the intervention was to what was intended (Moore et al., 2015). Dose and reach refer to the extent to which the intervention was implemented and sustained and reached the intended audiences (Moore et al., 2014). Process evaluations are meant to consider the ‘relations between implementation, mechanisms and context’ (Moore et al., 2014: p.1) as well as these aspects independently.

Literature on process evaluation tends to treat context as a defined and manageable aspect of research. For example, Moore et al., in summarising the MRC guidance on process evaluation, define context as ‘anything external to the intervention that may act as a barrier or facilitator to its implementation, or its effects’ (Moore et al., 2014: p2). Positing context as ‘external’ to interventions and as something that can be isolated, measured and accounted for accordingly has been problematised (Cohn et al., 2013; Mowles, 2014).

Theory driven process evaluation will be discussed in the literature in Part 2 (Oakley et al. 2006) as a way of considering and coupling the method with research hypotheses and philosophical underpinnings. This was the approach used in Part 2, where the diffusion of

innovations model for health care organisations was coupled with the method to explore rapid HIV testing variation in RHIVA2 general practices. This approach is desirable as the theoretical model chosen (diffusion of innovations in healthcare organisations) was developed through the systematic review of literature related to the diffusion of innovations and created a more robust method of investigation. Linking with some of the literature described in the ‘tinkering with trials’ section of the literature review, process evaluation has been positioned as another attempt to improve the conduct of trials on complex phenomena, to manage context, account for the ‘social’ and attempt to isolate key mechanisms that drive research outcomes.

The RHIVA2 trial aimed to implement a complex intervention in various sites using a clustered experimental design. There was significant variation in the uptake of testing. Process evaluation is well suited to combine various forms of data such as qualitative interviews, trial data and ethnographic field notes. In aligning with the key concepts informing this research, outlined earlier in the chapter, process evaluation within this study provides other accounts of the research event than provided by the trial but does not aim to entirely account for context or uncover true causal pathways regarding the intervention. Using this method, it is possible to learn more about the process of delivering rapid HIV testing and what may have helped or hindered practices and practitioners in delivering the intervention.

#### **4.6 Data sources**

A short description of the method and the data sources will be provided in each findings chapter. However, as data sources are called upon in different ways in each findings chapter, a brief guide to the data sources and data collection follows.

### *Ethnographic field notes*

Throughout the trial period, I acted as a member of the study team and was responsible for practice recruitment, training, monitoring and general liaison. As a result, I made numerous practice visits. I typed up notes from these visits when possible; additionally, informal conversations and email exchanges also took place with practice staff and the trial team. These materials form a part of the ethnographic field notes included as a part of the autoethnographic method. Over 100 hours of ethnography were undertaken. Field notes were compiled into binders including overarching field notes and reflections and those specific to each sub study.

### *Qualitative interviews*

*Policy stakeholders:* In-depth interviews were undertaken with a purposive sample of 14 policy stakeholders. Interviews were conducted at the participants' place of work during normal working hours in 12 of the 14 interviews; the other two were undertaken on Skype and the telephone. Written, informed consent was undertaken in all cases. Interviews lasted between 30 and 60 minutes. More details are provided in Part 1.

*Providers of rapid HIV testing:* Semi-structured interviews were undertaken with a purposive sample of 23 staff in 16 of the 20 intervention practices; the other four practices failed to respond to requests. Most were nurses or HCAs who primarily offered the rapid HIV test as a part of the New Patient Health Check. One practice manager, one clinical manager and one GP were interviewed in relation to their role in rapid testing (e.g., managing patients with reactive or indeterminate rapid test results, overall coordination of testing within the practice). Interviews were conducted at the practice during normal working hours and were one-to-one, except for two nurse and HCA pairs who asked to be interviewed together. Written, informed consent was obtained from all participants, who also completed a short demographic survey regarding age, ethnicity, length of time at current practice, part-time or full-time employment and previous HIV-related experience. Interviews lasted between 30 and 60 min. Interviews were conducted throughout the final eight months of the trial and into



the following year. Participants were given a £10 voucher as compensation for their time. More details are provided in Part 2.

*Patients testing HIV-positive with an initial INSTI test as part of RHIVA2:* Of the 11 potential patient participants testing positive with rapid HIV testing as part of the trial, five patients participated. Patients were approached by the HIV liaison nurse at the local hospital and consent was obtained prior to being introduced to me. Interviews took place at the local hospital and lasted between 30 and 60 minutes. Written, informed consent was obtained in all cases. More details are provided in Part 3.

#### *Trial performance at practice level*

Practice-level performance data were collected through the remotely accessible electronic record systems used in participating practices. These were the EMIS and VISION systems (EMIS, 2015; In Practice Systems, 2015). Through electronic management, the RHIVA team was able to gather monthly testing numbers for each participating practice. When the trial was completed, monthly data was aggregated and used to produce the trial findings. Practices were allocated to trial arms using the minimisation criteria of practice size, index of multiple deprivation score and male level of serology HIV testing in the years prior to the trial. These criteria, along with other practice-level criteria were compiled while gathering data to inform the four practice level case studies presented in Part 2. More details are provided in Part 2.

#### **4.7 Ethics and governance**

The RHIVA2 trial was approved by Camden and Islington Community Research Ethics Committee (09/H0722/67). The trial is registered as ISRCTN Registry number: ISRCTN63473710 with the date assigned: 22 April 2010. Ethical approval for the PhD qualitative research for the policy, patient and provider studies was gained from Bloomsbury National Research Ethics Service committee (11/LO/0324) in April 2011 with an amendment in December 2013. Queen Mary University of London acted as the sponsor for the research undertaken: ReDa 007610. All participants provided written, informed consent to participate in the research. The information sheet and consent form are appended

(Appendix 3). Care has been taken to aim to anonymise participants. Details have been altered and names changed.

#### **4.8 Patient and public involvement**

Efforts were made to include patients and the public in the formation and sharing of the research presented in this thesis. To a degree, these activities formed a part of the methodological approach as they involved receiving feedback on study design, analysis and plans for dissemination from groups with an interest in the research. I met regularly with patient representatives throughout the PhD, discussing my emerging research and gained feedback and best practice on issues such as recruitment and compensation, for example. I also presented my work-in-progress to various HIV-related community groups and organisations so as to share and encourage discussion about my findings. On one occasion I organised a research-training workshop where people living with HIV and research nurses learned about qualitative methods and coding. I used this session to discuss my approach to the patient-level study and gain comment on my analytical work. Undertaking patient and public engagement activities enriched the project and allowed me to remain engaged with the communities the work is meant to support.

## **PART ONE: Population screening and the logic of normalisation for HIV**

Part 1 of the thesis explores the policy context for RHIVA2. As described in the background chapter, the *2008 National Guidance for HIV Testing in the UK* (2008 National Guidance) recommended all women and men registering with primary care in highly endemic areas be considered for an HIV test. In the coming chapters I will explore how this recommendation was enabled and justified and some of the key discourses circulating at the time of the policy and the RHIVA2 trial. Much of Story 1, population screening for HIV and the logic of normalisation, is described here. I begin with a review of some literature related to screening and diagnosis before going on to describe the data sources informing Part 1 of the thesis. I will then present two findings chapters (Chapters 6 and 7).

In Chapter 6 I present the first findings chapter of the thesis. Here, I explore the justification for the 2008 National Guidance, the impetus behind RHIVA2. Using Kingdon's policy windows theory and Wilson and Jungner's principles for the early detection of disease, I call on 14 in-depth policy interviews and the 2008 National Guidance policy document to explore how the policy was justified and upheld (Kingdon, 2003; Wilson and Jungner, 1968). I find that four, what I term, 'micro-streams', converged to enable the 2008 National Guidance recommendations and subsequently the RHIVA2 trial. It also becomes apparent that population screening for HIV fulfills the majority of Wilson and Jungner's principles for the early detection of disease. This chapter acts as a theorised background chapter, with findings related to how the RHIVA2 trial came to be and the overall public health aims informing the study.

In Chapter 7, I further explore the policy stakeholder interviews and analyse four key policy documents circulating at the time of RHIVA2. A discourse analysis, with reference to existing discourses in the HIV literature, reveals three key discourses circulating in the HIV policy community and informing RHIVA2. These include: the risk/surveillance discourse, the HIV normalisation discourse and the HIV generations and dynamism discourse. Together these discourses pattern perceptions, activities and experiences related to HIV and inform much of the logic of normalisation.

## Chapter 5: IDENTIFYING DISEASE: INTRODUCTION TO PART 1

### 5.1 Population screening for HIV

‘It’s not a black thing, it’s not a white thing, it’s not a gay thing, and it’s not a straight thing. Testing for HIV is everyone’s thing’ (Orasure, 2012, as quoted in Banda, 2014: p.13)

Screening forms a regular and significant part of contemporary medical practice. Be it smear tests, mammography, antenatal or cancer screening amongst others, the majority of citizens will undergo some form of screening in contemporary UK life. With rapid advances in testing and diagnostic technologies, screening has become more accessible and portable. It is now possible, for example, to test for HIV in the privacy of one’s home with a self-testing kit (THT, 2016). Much is present in a screening test; an intersection of systems, disciplines, diseases, individuals, practices and settings, touching on fundamental human concerns. For patients, a screening tests may relate to matters of life and death, relationships, access and onwards. For practitioners it may be a matter of logistics, accuracy, targets and providing good and thorough care. For public health officials and policy makers it may be a discussion of thresholds, statistics, budgets and timing. For all it is quite possibly a combination of many emotional, logistical, temporal, financial and relational factors.

Population screening is defined by the United Kingdom National Screening Committee (UKNSC) as:

‘a process of identifying apparently healthy people who may be at increased risk of a disease or condition. They can then be offered information, further tests and appropriate treatment to reduce their risk and/or complications arising from the disease or condition’ (Armstrong and Eborall 2012: p.162)

The line between screening and diagnosis can be a fine one (Kaufert, 2000), as was the case in RHIVA2<sup>6</sup>. Implicit within screening programmes is the possibility of false results. This introduces themes of uncertainty and liminality, which are present in much of the sociology of screening literature (Armstrong and Eborall, 2012). The testing of an asymptomatic

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<sup>6</sup> While patients were made aware that a confirmatory test was required before being told they are definitively HIV-positive, a patient with a reactive rapid test is nonetheless left looking at the material test with a visible HIV test result and initiated on a pathway of care as if they were HIV-positive.

population for the presence or potential of conditions and diseases represents an important aspect of what some consider ‘the new public health’ where there is emphasis on prevention, early detection and patient choice (Tulchinsky and Varavikova, 2010). Seminally, in 1968, Wilson and Jungner produced criteria for the implementation of screening which continue to mark the conditions in which screening is seen as appropriate. The criteria are outlined by Mant and Fowler in their 1990 paper in the British Medical Journal entitled ‘*Mass screening: theory and ethics*’. The criteria are roughly summarised in the quote below and listed in Box 1:

‘the rules are essentially as follows ‘the disease should be common and serious, its natural history should be understood; there should be a good screening test; acceptable treatment should be available; this should favourably influence the outcome’ (Mant and Fowler, 1990: p.916)

**Box 1.** Wilson and Jungner’s principles for the early detection of disease (1968)

**Wilson and Jungner’s principles for the early detection of disease (1968)**

- 1) The condition sought should be an important health problem.
- 2) There should be an accepted treatment for patients with recognised disease.
- 3) Facilities for diagnosis and treatment should be available.
- 4) There should be recognisable latent or early symptomatic stage.
- 5) There should be a suitable test or examination.
- 6) The test should be acceptable to the population.
- 7) The natural history of the condition, including development from latent to declared disease, should be adequately understood.
- 8) There should be an agreed policy on whom to treat as patients.
- 9) The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
- 10) Case-finding should be a continuing process and not a ‘once and for all’ project.

Wilson and Jungner’s criteria will be further discussed in Chapter 6, where they form a part of the analytical frame for findings presented.

Some sociological work on screening explores the assumptions and messages that may be present in a screening program. In their review on the sociology of screening for a special issue in *The Sociology of Health and Illness*, Natalie Armstrong and Helen Eborall discuss

the disparate and interdisciplinary literature on screening citing contributions from health psychology, social theory, sociology, philosophy and biomedical science (Armstrong and Eborall, 2012). Key literature is the work of David Armstrong on ‘surveillance medicine’ (1995) (Armstrong and Eborall, 2012). This work outlines a 20<sup>th</sup> century medical era replete with the concepts of danger, fear, deception and obedience transmitted through policies and practices that include the monitoring of healthy populations which imply that everyone is at ‘risk’ (Armstrong, 1995; Armstrong and Eborall, 2012; Kaufert, 2000). Patricia A. Kaufert’s discussion of mammography and cervical smear testing in her book chapter: *Screening the body: the pap smear and the mammogram* in Lock, Young and Cambrosio’s edited collection: *Living and working with the new medical technologies: Intersections of inquiry* (2000), explores these ideas through the lens of science and technology studies (STS). Kaufert situates screening historically and explores the varying ways screening can be presented and experienced, dependent on where and how one looks. Kaufert highlights elements of ‘surveillance medicine’ in her discussion of the transition of thought and medical practice from the differentiation of the well and unwell to practices enacting the idea of a knowledge external to the sensing body, yet to be uncovered. See this quote:

‘for modern screening, philosophy and practice requires agreement with a set of assumptions on the nature of disease which are in some ways counter-intuitive. Older, commonsense notions, which assume a relationship between feeling well and being well, needed to be replaced by the idea of the deceptive body, which may feel well, but is a hiding place for disease’ (Kaufert, 2000: p.170).

She continues with a discussion of morality and the imperative to test, citing the critical work of Deborah Lupton in: *The Imperative of Health* (1995). This work explores screening through a Foucauldian lens claiming it is hard to challenge due to its ‘manifest benevolent goal of maintaining standards of health’ (Hausman, 2011: p.91; Lupton, 1993).

Foucauldian, concepts including surveillance, discourse, governmentality and ‘technologies of the self’ as well as Nikolas Rose’s discussions (as informed by Foucault) of biocitizenship also feature in the screening literature (Rose, 2001; Banda, 2014; Armstrong, 2007; Lupton, 1995). ‘Biocitizenship’ refers to a concept that draws connections between someone’s biological status, for example, as diseased or not, and their conception of the self or identity, re-orienting ideas of what is to be a human. Linked to this understanding is the way that markets can exploit the body and identity through the marketing and consumption of

biomedical technologies such as drugs (Banda, 2014). Jonathan Banda illustrates this concept in his discussion of HIV home-testing, positing that such forms of self-screening create new divisions between people who are HIV-positive and those who have tested and those who have not (2014). He describes the latter as an increasingly problematised category of individuals:

‘the moral and social responsibility of HIV testing implicates biocitizens who are expected to self-monitor in order to improve their own health and to minimize the risk posed to others. Nevertheless, the expansion of testing options is also inexorably linked to the relationship of biocitizens to medical authority’ (Banda 2014: p.4)

The messaging on the untested body explored by Banda in relation to HIV and more broadly discussed by Armstrong, Lupton and others is relevant to contemporary approaches to HIV screening in the UK. Presently, the untested and the undiagnosed are represented as the most significant challenge in reducing transmission rates (PHE, 2014), particularly in light of the ‘treatment as prevention’ revelations, definitive as of 2011 (Cohen et al., 2011) (As described in Chapter 2: Background).

## **5.2 Sociology of diagnosis**

Screening and diagnosis form natural counterparts. In Jutel and Nettleton’s introduction to the special issue of *Social Science and Medicine* on the sociology of diagnosis, they summarise important concepts and literatures related to the experience and practice of diagnosing illness (2011). They suggest diagnoses as ‘a prism which absorbs and reflects a panoply of issues central to the experience and practice of medicine and health care’ (Jutel and Nettleton 2011: p.793). The authors explain how changing understandings of health and disease impacts diagnostic experiences, definitions and practices. Jutel and Nettleton outline how at present ‘diagnostic categories are less bounded with the dualism of disease and non-disease, collapsing in the face of new categorisations of potential disease and risk factors. Patients now bring expertise, knowledge and expectations to the clinic.’ (Jutel and Nettleton 2011: p.793). Diagnoses are productive events and bring much into being, for example, diagnosis validates what counts as disease and legitimates illness, it offers explanations and can facilitate access to resources; being diagnosed can cohere patient symptoms and enable access to the ‘sick role’, which impacts social structures and performances (Jutel and Nettleton 2011: p.793). The ability to provide or withhold a diagnosis also demonstrates and

upholds medical authority and represents operations of power and access which have significant effect on an individual's well-being (Jutel and Nettleton, 2011). The review suggests three major themes in the sociology of diagnosis. Calling on Blaxter, a seminal thinker in bringing forth a sociology of diagnosis, they propose considering diagnosis 'as category', 'as process' and 'as consequence' (Jutel and Nettleton, 2011: p.793).

Diagnosis as category describes how a diagnosis is an attempt to classify experiences and provide definitions. Seminally, Bowker and Star discussed diagnosis as a classification activity (1999). Such categories can be contested, withheld, imposed, convenient and variable in different spacio-temporal sites. 'Diagnosis as process' highlights how generative a diagnostic act can be, leading to further diagnoses or re-categorisations, bringing forth a series of health related actions and processes and inspiring changes in identity.

Emphasising the processual aspects of diagnosis also brings into view the temporal dimensions and the numerous actors, locations, and interpretations related to a diagnostic act and its effects. This may allow for different ontological understandings of disease to be acknowledged and demonstrate how 'reading and interpreting the body' is not a stable act, but contingent on locations, context, cultures and other 'more fluid aspects' (Jutel and Nettleton 2011: p.796). Schubert, for example, treats diagnosis as a practical accomplishment and a coordination of various categories, locations, actors and agentic roles (Schubert, 2011). Gardner et al. discuss diagnosis in reference to Foucault's theory of bio-power and describe the event as where 'the medical gaze delves into a body with concrete form, shape and colour' (Gardner et al., 2011: p.71). Here, they describe individuals as encountering 'various intertwining forces', both social and material, in a process of diagnosis. In making disease intelligible through diagnostic practices they call on Mol's ethnography of atherosclerosis to describe diagnostic acts as a 'patchwork singularity (Mol 2002: p.171)': 'since the intelligibility of the disease is the product of diagnostic practices, multiple practices enact multiple forms of the disease' (Gardner et al. 2011: p.71).

The third theme of 'diagnosis as consequence' highlights how diagnostic acts have consequences, particularly for those being diagnosed: 'A diagnosis can vindicate and blame,



can legitimate or stigmatise, can facilitate access to resources just as it can restrict opportunities. A diagnosis can be welcomed or eschewed.’ (Jutel and Nettleton 2011: p.797)

A nascent discourse on the ‘normalisation’ of HIV has been taken up and explored by social scientists with an interest in HIV (Persson, 2013; Mazanderani, 2015; Mattes, 2014; Philbin, 2014; Moyer and Hardon, 2014; McGrath et al., 2014; Flowers et al., 2013). Overall, this literature challenges the positioning of HIV as ‘any other illness’ and explores the complexities of interacting with an infection with such a socially and symbolically charged history. In Chapter 7 and Chapter 10, as the discourse of ‘normalisation’ becomes more apparent and patient experiences described, this literature will be further explored.

While the rapid HIV test has been presented as a ‘quick’ and ‘simple’ test that can easily be implemented within existing medical settings and practices, the literature described above begins to expound the ways screening programmes cluster, contain and enact structural, discursive and personal meaning while reinforcing medical authority and particular forms of citizenship. In presenting the policy-related findings chapters below, these themes are explored more explicitly in relation to RHIVA2.

### **5.3 Data sources**

The methods used in Part 1 of the thesis are described in detail in Chapter 4 of the thesis. I will now describe the data sources informing the findings presented in Chapters 6 and 7. Data sources include in-depth interviews with policy stakeholders, analysis of four key policy documents, and insights gained through the ethnographic method.

#### *In-depth interviews with policy stakeholders*

Interviews were undertaken with 14 stakeholders in the UK HIV policy community. Participants were sampled purposively. Inclusion was determined by the individual’s role in the development of HIV testing policy, recommendations from other participants, a review of relevant policy documents and my HIV policy knowledge from years in the field. Interviews

were held at a location convenient to the participant and lasted approximately 1 hour. All participants provided written informed consent. Most (n = 12) interviews were undertaken at the participant's place of work and on occasions where participants were not working locally, both the telephone (n = 1), and Skype (n = 1), were used. Participants were not provided with any compensation for their time but did receive a thank you card. All interviews were recorded and transcribed.

Interviews were semi-structured. A list of questions was drawn up and delivered to all participants with space to explore other topics as appropriate. The topic guide for the interview included:

- Overall role in HIV policy
- HIV testing policy and the 2008 National Guidance
- HIV testing policy in the UK
- Policy actors and processes
- Rapid HIV testing

Table 4 provides a description of participants and their role in HIV policy in the UK.

**Table 4.** Policy interview participants and their described role in UK HIV policy

	<b>Role</b>	<b>Organisation</b>
1	Senior position	Government body related to sexual health and HIV
2	Policy lead	UK HIV charity
3	HIV Consultant / Policy-maker	HIV consultant with a role in professional medical associations and government consultant roles
4	Senior position	Patient organization / HIV charity
5	Senior epidemiologist	National health organisation
6	Patient representative	London HIV clinic / Participant in policy guidance with various organisations
7	GP with specialism in HIV	HIV lead in a professional association / NHS
8	GP with specialism in HIV	Member of national medical associations / lead on HIV education programmes/ NHS
9	GP with specialism in sexual health / part time academic / active member of national medical associations	Academia / professional medical associations / NHS
10	Senior position	National HIV charity
11	HIV consultant and member of professional association	NHS/ member of professional association related to HIV and sexual health
12	Senior position	National health body
13	Academic with HIV specialism	Academia
14	Past public health consultant	NHS

### *Policy documents*

Policy documents were sampled based on their role in promoting the 2008 National Guidance recommendations, particularly, the offer of an HIV test to all new registrants in general practice in high prevalence areas. Document 1, *The UK National Guidelines for HIV Testing 2008* (2008 National Guidance) was the first piece of national guidance recommending this testing strategy and served as the benchmark for HIV testing policy in the UK until 2011. In an aim to evaluate the recommendations in the document, HPA pilots were undertaken and are reported in Document 2: *Time to test for HIV: Expanding HIV testing in healthcare and community services in England* (2011). This report extended the evidence set out in the 2008 National Guidance and contributed to justifying the development of the 2011 NICE guidelines on HIV testing for specific populations which comprise Documents 3 and 4: *Increasing the uptake of HIV testing among black Africans in England: NICE public health guidance 33*, and the *Increasing the uptake of HIV testing among men who have sex with men: NICE public health guidance 34* (NICE, 2011a) (NICE, 2011b). During this period were the strongest pieces of policy and clinical guidance regarding universal testing for new registrants in primary care in the UK. A brief description of each document follows.

*Document 1: The UK National Guidance for HIV Testing 2008* is the BHIVA, BASSH and BIS produced document that inspired the RHIVA2 trial. This 23-page document was seen as the foremost national guidance on HIV testing in 2008, until the arrival of NICE guidance in 2011. The objectives of the 2008 National Guidance were to:

‘facilitate an increase in HIV testing in all healthcare settings as recommended by the UK’s Chief Medical Officers and Chief Nursing Officers [1-4] in order to reduce the proportion of individuals with undiagnosed HIV infection, with the aim of benefiting both individual and public health.’ (BHIVA et al. 2008: p.1).

It is within this document that the approach evaluated in RHIVA2 was recommended:

‘An HIV test should be considered in the following settings where diagnosed HIV prevalence in the local population (PCT/LA) exceeds 2 in 1000 population (see local PCT data):

1. All men and women registering in general practice
2. All general medical admissions

The introduction of universal testing in these settings should be thoroughly evaluated for acceptability and feasibility and the resultant data made available to better inform the ongoing implementation of these guidelines.’ (BHIVA et al., 2008: p.5)

*Document 2:* The second document chosen for analysis is the HPA's: *Time to test for HIV: Expanding HIV testing in healthcare and community services in England* final report (2011). The 42-page report provides the results of eight pilot projects undertaken with the financial support of the DoH, to evaluate HIV testing in hospital, primary care and community settings. This work was undertaken to 'assess the ways in which the testing guidelines might be best implemented' (HPA, 2011: p.2) and essentially to establish a stronger evidence base for the national testing guidance, and determine aspects of feasibility and cost effectiveness (HPA, 2011). The pilots related to general practice were described in Chapter 2:Background, Section: 2.3.

*Documents 3 and 4:* The National Institute of Health and Care Excellence (NICE) jointly produced 2 pieces of guidance related to targeted testing: *Increasing the uptake of HIV testing among black Africans in England: NICE public health guidance 33*, and the *Increasing the uptake of HIV testing among men who have sex with men: NICE public health guidance 34*. Produced in 2011, the guidelines incorporate much of what was recommended in the 2008 National Guidance with specific consideration of the UK's most highly endemic groups for HIV. These also form the 2<sup>nd</sup> and 3<sup>rd</sup> policy documents analysed. These guidance documents are aimed at NHS and other commissioners, managers and practitioners who are directly or indirectly involved with, and responsible for, increasing the uptake of HIV testing among black African and MSM communities (NICE , 2011a; NICE, 2011b). They also mention local authorities, the wider public, private, voluntary and community sectors as well as both black Africans in England and MSM as audiences. Both sets of guidance, 54 and 58-pages respectively, aim to increase the uptake of HIV testing, to reduce undiagnosed infection and prevent HIV transmission in black African and MSM communities in England. Both sets of guidance also promote the 2008 National Guidance as seen in the quote below:

'In areas where more than 2 in 1000 population have been diagnosed with HIV:

- primary care and general medical admissions professionals should consider offering and recommending an HIV test when registering and admitting new patients (this is in line with BHIVA guidelines)' (NICE 2011a: p. 13)

## **Chapter 6: AN EMPIRICAL STUDY OF THE POLICY CONTEXT FOR THE HIV TESTING OF NEWLY REGISTERING PATIENTS IN PRIMARY CARE IN THE UK**

### **6.1 Introduction**

This chapter explores questions related to the development of the *UK National Guidance for HIV Testing 2008*, jointly produced by BHIVA, BASHH and BIS (2008). This was the guidance prevailing at the time of the RHIVA2 study and formed the policy context in which practices were implementing the intervention. I aim to determine why HIV testing in primary care for new registrants in highly endemic areas was considered as a policy objective. In providing a broad description of the context for the guidance and therefore the findings of this study, micro and macro factors are pulled apart and insights regarding the policy process are gathered. This paints a picture of the public health and policy terrain of which the RHIVA2 trial formed a part. RHIVA2 trial was dually tasked with implementing and evaluating the recommendation simultaneously. I use Kingdon's policy windows theory to delineate the converging elements that led to an increased push for the early detection of HIV and a subsequent renewed interest in HIV testing (Kingdon, 2003). I will also evaluate the decision to recommend opt-out testing to the general population using Wilson and Jungner's principles for the early detection of disease (Wilson and Jungner, 1968).

In this chapter, I take the themes enabling the policy, in a sense, at face value, without in-depth consideration of how these themes may have been constructed through discourses, power relations and broad philosophical assumptions related to the organisation and values of UK society and of evidence more broadly. I feel this is an important move to enable an understanding of the policy and the trial from the perspective of the research team and the UK HIV policy network. In the next Chapter, Chapter 7, I will explore discourses operating within the policy network which allow for a deeper discussion of what else may have been at play to enable this policy shift.

## 6.2 Theoretical Frame

### *Kingdon's policy windows*

In 1984 John Kingdon published: *Agendas, Alternatives, and Public Policies*, a case study of policy making practices in the United States. Kingdon pays close attention to 'agenda setting', an area he claims was widely overlooked in academic policy studies at the time (Kingdon, 2003). He aimed to understand why some items make it onto the policy agenda and others not, how such problems are defined, why some policy options are prioritised, others neglected, and the role of politics within these processes (Kingdon, 2003: p.xxvi). This led to the development of the policy windows theory of agenda setting. In later years the theory has been extended by Nikolas Zahariadis, termed multiple streams, and applied to the wider policy process, not just agenda setting (Zahariadis, 2007).

Kingdon describes the policy process as including a set of practices. First, setting the agenda, second, specifying options or alternatives from which a choice is made, third, an authoritative decision regarding the policy choice and finally the implementation of the decision (Kingdon, 2003). Agendas are defined as the list of items or problems policy-makers, civil society or politicians are paying attention to. What is on this agenda is heavily influenced by who the active participants related to these items might be and the 'processes by which the items have come to prominence' (Kingdon, 2003:p.15). Other factors in agenda setting may be events that highlight particular problems, or a change in an important indicator related to the policy item. Additionally, specialists and experts may reach a breaking point on particular issues after accumulating substantial knowledge and analysis; this may culminate in a policy issue coming to the fore. Finally, political factors may also play a key role, for example new political players, or the rise of interest groups, may lead to the inclusion of new policy items (Kingdon, 2003).

Kingdon describes the three processes of problem recognition, generation of policy proposals and political events as able to act as facilitators or barriers to policy formation and setting of the agenda. While Kingdon noted that the more one studies policy 'the more one concludes

that attempting to pinpoint a single origin is futile. Instead, a complex combination of factors is generally responsible for the movement of a given item into agenda prominence' (Kingdon, 2003: p.76), he goes on to summarise his observations and puts forth the policy windows theory. Here the streams of problems, proposals and politics are defined as independent and 'coequal' elements of the policy puzzle, converging and diverging in ways that support or detract from policy possibilities. Kingdon describes the streams below:

'These three streams of processes develop and operate largely independent of one another. Solutions are developed whether or not they respond to a problem. The political stream may change suddenly whether or not the policy community is ready of the problems facing the country have changed... The streams are not totally independent however. The criteria for selecting ideas in the policy stream, for instance, are affected by a specialists' anticipation of what the political or budgetary constraints might be... Despite hints of connection, the streams are still largely separate from one another, largely governed by different forces, different considerations, different styles.' (Kingdon, 2003: p.88)

The problem stream relates to the acknowledgement and recognition of problems or items for the agenda. The policy stream includes the proposed solutions for tackling said problem, and the politics stream includes the national mood and political climate surrounding the issue. New or changed political appointments, public events and general political jostling can impact the political stream. The theory suggests that when the three streams of problems, policies and politics are successfully aligned, often by a 'policy entrepreneur' (someone who champions and facilitates implementation of new ideas into practice) a policy window is said to open (Kingdon, 2003:88):

'The key to understanding agenda and policy change is their coupling. The separate streams come together at critical times. A problem is recognized, a solution is available, the political climate makes the time right for change, and the constraints do not prohibit action...I label an opportunity for pushing one's proposals a 'policy window' – open for a short time, when the conditions to push a given subject higher on the policy agenda are right. But the window is open for only a while, and then it closes.' (Kingdon, 2003: p.88)

Zahariadis has critiqued Kingdon's model, suggesting that perhaps the streams are not independent of each other, that there is a lack of clarity around the role of the window in the coupling of streams, the entrepreneurial strategy for coupling, solutions following an incremental evolution in the policy stream and the lens being merely a heuristic device (Zahariadis, 2007).

Despite these potential limitations, Kingdon's model proved a useful analytical tool for exploring the occurrence of the 2008 National Guidance, which appeared to follow a fairly rationalistic course of responding to a policy problem with feasible policy solutions. The exploration of discourses inherent to the policy, in Chapter 7, allows for a more critical discussion of the policy objectives.

*Wilson and Jungner's principles for the early detection of disease*

'in theory, screening is an admirable method of combating disease ... [but] in practice, there are snags' (Wilson and Jungner, 1968:p.7).

I will now introduce a contrasting set of criteria related to public health policy, with emphasis on screening. While discussing the sequences of evidence, events and arguments that enabled Kingdon's 'policy window' regarding opt-out HIV screening in primary care to open, I will also consider Wilson and Jungner's principles for the early detection of disease. Including Wilson and Jungner allows for another level of analysis of the policy, which sits within the epidemiological literature. The criteria are considered a longstanding and widely accepted best practice guide for the justification of screening activities in healthcare (Andermann et al., 2008).

Determining when a population screening approach is appropriate requires some evaluative criteria. A primary concern in screening has been the ethical hallmark of 'do no harm'. In an attempt to gather clarity and guidance on when a screening approach would be beneficial, the World Health Organisation (WHO), in 1968, commissioned Wilson and Jungner to assemble criteria. Summarised in the literature review, but reproduced below in Table 5 with added description, the criteria raise key considerations for justifying a screening program and consider dimensions of feasibility, patient wellbeing, economic impact and the appropriateness of the disease aetiology in relation to screening techniques.



**Table 5.** Wilson and Jungner’s principles with description (1968)

	<b>Principle</b>	<b>Description</b>
1.	The condition sought should be an important health problem.	High prevalence of disease is not a necessary factor. Individual, community and social factors should be considered alongside disease prevalence.
2.	There should be an accepted treatment for patients with recognised disease.	In order to avoid harm, acceptable treatments should be available for those screened for disease. Key questions: 1) Does treatment at the pre-symptomatic border-line stage of a disease affect its course and prognosis? 2) Does treatment of the developed clinical condition at an earlier stage than normal affect its course and prognosis?
3.	Facilities for diagnosis and treatment should be available.	Those diagnosed with early stage disease should be able to access treatment; this may be in terms of clinical provision, cost or other accessibility factors.
4.	There should be recognisable latent or early symptomatic stage.	The disease must have a latent period sufficient enough to detect the illness through screening programmes. If it does not, the value of screening is limited, as symptoms will cause individuals to seek health services.
5.	There should be a suitable test or examination.	Tests may be divided between screening and diagnostic tests. While screening tests may have a larger margin of error, this margin must be reasonable and be more likely to deliver false positive than false negative results.
6.	The test should be acceptable to the population.	Aspects such as the nature of the risk of the disease, the level of public education regarding the disease, and the ease of use of the diagnostic or screening test may be important factors.
7.	The natural history of the condition, including development from latent to declared disease, should be adequately understood.	Understanding the natural history of the infection, and any pathological changes in the disease over time is important, as is determining how such changes may interact with available treatments. That treatment remains relevant to whom and when and under what conditions is important to determine when possible.
8.	There should be an agreed policy on whom to treat as patients.	‘Borderline subjects’ must be clearly defined. This may be variable based on setting, clinician and individual case however whenever possible treatment parameters should be clearly identified, as should follow up procedures for ‘borderline subjects’.
9.	The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.	Early detection lengthens the productive life of patients; it may also allow health services to avoid costly interventions and specialist care. Wilson and Jungner indicated that economic assessment may not be easy to determine and that screening programmes may be costly initially or even in the long term. Technological shifts are acknowledged as opportunities in cost reduction.
10.	Case-finding should be a continuing process and not a ‘once and for all’ project.	One-off screening may be of little value. Determining how often populations should be screened is important in determining the value and cost of such programmes.

### 6.3 Analysis

Transcripts and the 2008 National Guidance policy document were coded twice. In the first instance I applied Kingdon's policy windows theory, broadly identifying themes related to the problem, policy and politics streams. I then applied Wilson and Jungner's criteria to the data to pull out themes related to the 10 principles. It became evident early in my analysis that the application of Kingdon's policy streams theory would explain and describe some but not all of the themes emerging in the data. Accordingly, I sought to supplement my theoretical approach with the identification of further 'streams' that appeared important to the development of the guidance. The primary thematic analysis of interview transcripts and policy documents identified approximately 17 key themes related to Kingdon's model. For manageability, I divided these 17 themes into four, what I have termed, 'micro-streams'.

The micro-streams identified include 1) *epidemiology and public health*, 2) *health setting factors*, 3) *treatment, technology and techniques* and 4) *socio-cultural dimensions of HIV infection*. In the findings I will describe the micro-streams and the themes that comprise them. The 'micro-streams' categorise the themes but can also be discussed in relation to the three main streams as outlined by Kingdon, the problems, policies and politics streams. The delineation of these 'micro-streams' formed emergently while working through the findings related to the policy. Through this analysis and demonstration, I hope to illustrate how the policy window enabling the 2008 guidance was opened. The consideration of Wilson and Jungner's principles alongside this analysis helps determine the rationale for a population screening approach. With Wilson and Jungner's criteria I analysed the data for points of fulfilment and contention. The results are displayed in Table 6, using a colour-coded system, as well as described alongside the micro-streams in the presentation of the findings.

## 6.4 Findings

### *Micro-stream 1: Epidemiology and public health*

The micro-stream of *epidemiology and public health* outlines key indicators in HIV that signified a need for emphasis on the early detection of the virus. The picture was one where the importance of early detection and access to treatment was becoming evident through the emergence of large, reliable studies, local data and a shifting general tone. This data indicated that late-diagnosis, HIV testing, and access to treatment were important factors in reducing HIV-related mortality and morbidity. The ‘post-HAART era’, referring to the period from which highly active anti-retroviral therapies (HAART) have been widely available demarcates a new generation of HIV treatment and survivorship (Newman et al., 2010). The transition of HIV from a ‘death sentence’ to a treatable condition is discussed later in the chapter and informs an important part of the ‘logic of normalisation’, which comprises a central story in this thesis. The logic surrounding screening is largely informed by the rationale assigned to detecting latent disease in non-health seeking populations.

The data described in this micro-stream, when brought together, created the evidence base for a pressing policy problem. Kingdon cites changes in key indicators as a main factor in problem definition and the ability of the ‘problem stream’ to converge with the politics or policies stream (Kingdon, 2003). A government employee describes the accumulating evidence:

‘I mean it was opportunistic. We had the time, we had some money, there were, as I say, all these drivers coming around the guidelines...that’s right, the BHIVA guidelines, international influences, the audit report from BHIVA, and this sort of, I suppose groundswell of thinking, well our data’s so good, we know we’ve got these late diagnoses, what’s happening? What can we do?’ (Employee at government agency concerned with health)

What is described in this micro-stream also works to fulfill Wilson and Jungner’s first principle: the condition sought should be an important health problem (1968). The themes described below were identified within the 2008 National Guidance itself, as well as by policy makers throughout their interviews. I will now describe this rationale in relation to

HIV screening and the arguments present in the HIV policy community, as informed by public health and epidemiological data.

### *Undetected and undiagnosed HIV*

Unwitting transmission and undiagnosed HIV have become important public health priorities in light of the changing treatment possibilities for HIV-positive individuals. Approximately one-third of people living with HIV in 2006 were estimated to be undiagnosed (HPA, 2007). If individuals are unsuspecting of an HIV infection there is little impetus to seek out testing or request a test when presenting at health services. Undiagnosed HIV has also been acknowledged as a major cause of continued transmission of the virus (Vernazza et al., 2008; Cohen et al., 2011). When individuals are aware of their HIV status they tend to alter 'risk' behaviours (unprotected sex, needle sharing), reducing transmission (BHIVA et al., 2008). The finding (increasingly demonstrated in high impact studies) that treatment can act as prevention and virtually render HIV non-infectious (when medications are properly adhered to and HIV-positive individuals are able to maintain an undetectable viral load) has been one of, if not the, most dramatic shifts in the HIV landscape in recent years (Vernazza et al., 2008; Cohen et al., 2011). This repositioning of risk away from HIV-positive individuals and onto those unaware of their HIV status will be further discussed in Chapter 7.

Additional data indicates that late diagnosis negatively impacts upon morbidity and mortality. The HPA cites 2006 data indicating that 33% of new HIV diagnoses were at a late stage and that it was more likely for heterosexual men and women to be presenting late, with heterosexual men thought hard to reach with existing health promotion techniques (HPA, 2007). These findings added impetus to the screening approach which aims to bring the wider population into view.

### *Mortality and morbidity and late-presenting HIV*

Participants in the in-depth interviews cited the *2006 British HIV Association National Audit* as a turning point in a growing recognition of the importance of early diagnosis of HIV

(BHIVA, 2007). The audit is the first piece of evidence mentioned in the 2008 National Guidance:

‘A national audit by the British HIV Association (BHIVA) showed that of deaths occurring amongst HIV-positive adults in the UK in 2006, 24 per cent were directly attributable to the diagnosis of HIV being made too late for effective treatment.’ (BHIVA et al., 2008: p.2)

Within the growing body of evidence in support of early HIV detection, the 2006 BHIVA mortality audit brought the UK population into sharp focus with the presentation of results clearly demonstrating the role of late detection in local HIV-related deaths. A GP with an interest in HIV explains:

‘clearly the driving force behind all of this is the undiagnosed population of HIV and I think that one of the key drivers for this work was really the publication of the BHIVA audit, which was 2006 I think. The BHIVA audit looking at deaths amongst HIV-positive patients and which highlighted not only was late diagnosis the single biggest cause of death but also that these people, it wasn’t that they weren’t attending health services, they were attending and with the benefit of hindsight were clearly presenting with conditions that were related to their HIV but they weren’t being offered HIV tests. And they were often presenting in a general practice setting.’ (GP with key role in the development of the UK National Guidelines for HIV Testing 2008)

### *Impaired response to medication*

Definitions around ‘late diagnosis’ have evolved. HIV and AIDS have been defined through the demarcation of particular levels of immune response in the body, CD4 counts and viral loads, as well as the presence of HIV antibodies (Wailoo, 1997). Individuals with HIV who are detected at a late-stage of the infection demonstrate an impaired response to medication and require significantly more medical care (BHIVA et al., 2008; Stöhr et al., 2007). This raises the cost and health care burden, adding not only to the definition of the ‘problem’ and the economic argument, which form a part of Wilson and Jungner’s criteria, but contributing as well to the ‘politics’ stream of Kingdon’s model.

‘Late diagnosis of HIV infection has been associated with increased mortality and morbidity (7), impaired response to HAART (8) and increased cost to health care services (9).’ (BHIVA, 2008:p.2)

### *Missed opportunities for testing*

Of particular relevance to the guidance was data indicating that individuals attending general practice in the UK who were infected with HIV were routinely seeking medical care and opportunities to test were present, yet patients were not being offered tests (BHIVA et al., 2008). In some cases, patients were presenting (sometimes repeatedly) with conditions indicative of HIV infection (Sullivan et al., 2005; Wellesley et al., 2015). This finding appeared central to the push for increased testing in primary care.

### *International trends*

The Centres for Disease Control (CDC) in the United States were the first to suggest opt-out HIV testing for new registrants in health services (CDC, 2006). Their data also contributed to the threshold of 2/1000 included in the guidance and the economic analysis indicating likely cost effectiveness (CDC, 2006). The CDC were also first to make recommendations around abbreviated counselling and consent procedures for HIV testing and are widely acknowledged as leaders in HIV science and practice internationally, as described by a public health consultant below:

‘The CDC, like Public Health England, had to roll and review the evidence into feeding the evidence into policy. And both of them are also involved in discussing at a global level which WHO and the - what is it? UN AIDS in Geneva. So there are policy trends... So...in many respects this could be a trend within the UK and the US leading. France have also had similar policies. The Netherlands have had similar policies so...’ (Public Health Consultant at national health organisation)

### ***Micro-stream 2: Treatment, technology and techniques***

The treatment, technology and techniques surrounding HIV are high-tech and rapidly changing. Treatment possibilities have largely dictated the acceptability of practices surrounding HIV. New rapid diagnostic tests, more effective HIV drug therapies, a shift towards treatment and prevention, and the general movement of HIV from a ‘life sentence’ to a treatable medical condition has allowed for the emergence of different testing practices,

including rapid and point of care testing and abbreviated consent and counselling procedures. These broad changes in HIV treatment, technologies and techniques shape the policy terrain and the 2008 National Guidance reflects and was enabled by these shifts.

The factors outlined in this micro-stream contribute substantially to the feasibility of policy proposals, as contained in Kingdon's 'policy stream': factors that facilitate reasonable and practicable solutions to the policy problems and promote the opening of the policy window (Kingdon, 2003).

In regards to Wilson and Jungner's criteria, a suitable test and examination that is also acceptable to the general population form Principles 5 and 6 for the early detection of disease (1968). The discussion of treatment, technology and techniques and what is now available in HIV treatment and care also implies an advanced understanding of HIV aetiology, including the transition from latent to advance stage disease. Wilson and Jungner highlight such an understanding of the disease subject to screening as essential in Principles 1 and 6 of the criteria (1968).

#### *HIV drug treatment possibilities*

Easily one of the most important shifts in HIV has been the continual improvement of HIV therapies to prolong and improve the lives of HIV-positive people. These therapies are in a constant process of improvement and expansion. The amount and frequency with which individuals take medications has reduced along with the severity of side effects. The opening line of the 2008 National Guidance highlights this:

‘Whilst the availability of highly active antiretroviral therapy (HAART) has transformed the outcome for individuals with HIV infection, there continues to be significant and avoidable morbidity and mortality relating to HIV infection in the UK.’ (BHIVA, 2008: p.2)

While less evident in 2008, there was some evidence that that treatment was likely to impact prevention, though it was not until 2011 that definitive high level evidence confirmed the findings, forever changing the HIV landscape (Vernazza et al., 2008; Cohen et al., 2011).

### *Rapid tests*

The first rapid HIV test was developed in the United States in 1992 (Kaiser Foundation, 2014). Rapid tests are considered single use, disposable devices, using minimal reagents that provide an HIV test result in under-60 minutes (CDC, 2007). They are meant to be technically simple to operate, performed near patient and use whole blood or saliva fluid specimens. The first rapid HIV finger-prick test was developed in 2002, gaining approval by the Clinical Laboratory Improvement Amendments (CLIA) waiver in 2003. The first saliva-based test, with CLIA approval, followed in 2004 (Kaiser Foundation, 2014). HIV testing is constantly in transition. From 1985 when the first HIV test was licensed (the ELISA test), to the present when in 2013 the first rapid test that detects both antigens and antibodies as well as distinguishes between acute and established HIV-1 infection was developed, there is constant test development in the pipeline (Kaiser Foundation, 2014).

Presently, the detection possibilities for HIV continue to improve, making HIV testing more portable and self-contained, moving testing for HIV further out of the clinic and into the private sphere. Home testing was approved in the UK in 2014 and the first commercially available rapid tests available for purchase to the general population were legally available in stores from April 2014 (Stephens, 2014).

### *Consenting and counselling*

When delivering an HIV diagnosis meant telling someone that they were on an accelerated path towards death, HIV testing held a different status. The surrounding practices aligned with the gravity of the infection. Much debate and consideration took place regarding when, how and who to test as well as who was suitably qualified to offer testing (Baggaley et al., 2012). Pre-test counselling and preparation was considered best practice and lengthy consenting procedures ensured that individuals knew the impact testing and a positive diagnosis might have (Cohan, 2009). While it would be inaccurate to assume that receiving an HIV diagnosis today is not a serious and life-changing event, in the UK the diagnosis need not dictate the same steady trajectory towards mortality. Following the Centre for Disease Control (CDC) in the United States in 2006 who recommended abbreviated pre and post-test



counselling procedures and promoted opt-out verbal consent practices for testing there was a ripple effect across other nations with similar epidemiological and health system profiles, including the UK (CDC, 2006; BHIVA et al., 2008). These changes allowed more diverse health care personnel to offer HIV testing, a shift evident in the RHIVA2 trial where health care assistants conducted the majority of rapid tests.

As indicated in the 2008 guidance:

‘The primary purpose of pre-test discussion is to establish informed consent for HIV testing, lengthy pre-test HIV counselling is not a requirement, unless a patient requests or needs this (1-4). The essential elements that pre-test discussion should cover are:

- the benefits of testing to the individual.
- the details of how the result will be given

This approach has been successful in GU and antenatal clinics and is generally acceptable.’ (BHIVA et al., 2008: p.11)

This demarcates a large shift in historic HIV testing approaches where there is no mention of the psychosocial aspects of delivering an HIV-positive result and emphasis on counselling practices for HIV testing is not encouraged. This move also forms an important aspect of the ‘normalisation’ of HIV and a move away from historic exceptionalism.

### *Ability to be evaluated*

The 2008 National Guidance suggested that pilot studies explore the effectiveness of the recommendation, which was taken up by the HPA in 2011 which the funding of the aforementioned pilots for testing in non-traditional settings (BHIVA et al., 2008; HPA, 2011). The ability of the guidance to be evaluated and measured for impact was understood as key in contributing to the evidence base. RHIVA2 was also developed for this purpose, to lend ‘gold standard’ evidence to the recommendations. Less tangible recommendations that are not quantifiable or able to be tested through experimental designs may not be as appealing to policy makers (Kingdon, 2003). The benefit in evaluation of screening programmes is also implicit in Wilson and Jungner’s criteria.

### *Micro-stream 3: The health care setting*

The organisation of the UK health system is an important contextual influence on the ability to develop and implement policy options. In the case of HIV testing in primary care, organisational aspects of the UK health care system make recommendations such as the offer of tests to all new registrants more feasible. As outlined by Kingdon in his discussion of the policy streams, an important aspect of the converging ability of the policy stream, that is, the proposed solutions to the policy problem, is feasibility (Kingdon, 2003). That new policies can work with pre-existing systems and infrastructure, and are able to streamline with contemporary practices and policies, plays an important role in implementation and acceptance of new directives.

Wilson and Jungner highlight the important role of acceptable facilities for diagnosis and treatment in Principle 3 (1968). Here, primary care takes on this role and is centralised for its position in the community and inclusion of practices such as new patient registration procedures and checks, sites of obvious consideration for the implementation of screening.

#### *New Patient Health Checks*

New Patient Health Checks (NPHC) were routine practice in most GP practices participating in the RHIVA2 trial (39/40), though were variable in their make-up and offer (McMullen et al., 2015). Typically, the NPHC includes the collection of baseline data on health and lifestyle from new registrants by asking a series of questions (NHS, 2014). Data collection is prompted by a computerised clinical system and information is entered on the patient record (Robson et al., 2015). The provision of this service lends itself to the opt-out offer of tests. This enhances the feasibility of the recommendation of offering new registrants in high prevalence areas HIV testing and for screening strategies in general. This health setting factor may have contributed to the perceived feasibility of the guidance. The GP in the quote below describes the important role of the new patient health check as well as its transition in UK healthcare policy (her description, in 2014, reflects shifts since the time of the trial):

‘But of course new registration checks are no longer part of what we have to deliver, right? So good practices do them and I worked in good practices that offered them and we would make sure they were worthwhile because they’ve got a whole lot of other stuff in them as well. So that’s another thing that doesn’t work for me. I’ve forgotten this, which is new registration checks are not the norm in practice or practices. So when you’re commissioning on a return of new patient checks... We used to get paid for new patient check in the old days... How on earth do you run HIV screening without a new patient check? (GP with role in HIV on professional medical associations)

What the GP describes here is variability in the offer and make up of new patient health checks, largely brought on due to policy changes since the time of the trial.

#### *Universal health care / Free HIV treatment*

‘In a sense, having a NHS in the UK could facilitate implementation of some policies and can facilitate an early uptake of, or early implementation of evidence based interventions.’ (Public health consultant with national health organisation)

Universal access to healthcare on the NHS means that UK residents can access medical services free of charge. This includes primary care, secondary care and Genito-Urinary Medicine (GUM) clinics. There is no charge to the patient for HIV testing and treatment is freely available if one is found to be HIV-positive. Previously, if someone was diagnosed HIV-positive and not a legal UK resident, they might experience complications accessing free medical treatment for an HIV infection (Anderson, 2012, personal communication, July 12). At the time of the RHIVA2 trial and the release of the 2008 National Guidance, some boroughs offered free treatment for any HIV-positive individual while other boroughs only covered UK residents. In 2012, legislation was passed indicating anyone in the UK regardless of their immigration status could access free HIV treatment (MRN, 2012). At the time of the guidance and the trial, the borough in which the trial was being rolled out offered free HIV treatment to any individual living with HIV, regardless of immigration status.

Wilson and Jungner discuss how testing should be acceptable to the general population, if treatment was not widely available and accessible to the general population, which may

include undocumented migrants, then some may consider screening to be inappropriate (1968).

### *Existing and precedence setting policy*

Existing policies in the UK also demonstrated wide scale acceptance and the successful implementation of HIV screening approaches. Antenatal screening for HIV has been widely acknowledged as one of the UK's most successful HIV testing policies. This policy is widely promoted and, to a degree, celebrated as demonstrative of the wide-scale acceptance and implementation of HIV screening strategies (BHIVA et al., 2008: p.2) A community HIV worker describes the success as well as comments on the 'logic of normalisation':

'It sounds a bizarre thing, but normalise HIV testing as much as possible. I think that one of the things that has been really successful if we are looking at testing has been the antenatal testing, where women now opt out of testing. We do a pregnancy project and we see quite a few women coming through who are diagnosed in pregnancy. So we know we are catching people there, people who would otherwise go unnoticed. That is a huge success. So how can we replicate that model in other settings?' (Lead at HIV-positive patient group)

Opt-out testing for HIV has also been shown to be widely accepted by the UK population and abroad; much of the introductory paragraph in the 2008 National Guidance discussed this:

'The only randomized controlled trial published to date (13) on testing methods shows that a universal 'opt-out' approach to HIV testing in antenatal patients was acceptable, did not cause anxiety and had a higher uptake than other methods' (BHIVA et al., 2008: p.3)

'In the USA in 2006 the Centers for Disease Control and Prevention (CDC) recommended opt-out testing for all individuals aged 13-64 presenting to any healthcare facility (mainly Emergency Rooms) for any reason (18).' (BHIVA et al., 2008: p.2)

In principle 6 Wilson and Jungner emphasise the importance of the acceptability of testing to the wider population and list this as one of their essential criteria for screening (1968).

### *The role of the GP*

My field notes indicate numerous conversations regarding the role of the general practitioner in HIV care at both policy-related events and within general practices. The feeling was that GPs had a larger role to play in HIV, that their direct access to the community and role as the first point of contact for health seeking citizens had untapped opportunity for improving HIV detection and care. Additionally, the transition of HIV from an untreatable, deadly infection to a chronic, treatable medical condition meant that HIV-positive individuals would theoretically rely less on specialist services and could be routinely managed by non-specialist GPs, particularly when presenting health concerns that appear unrelated to HIV. Coupled with the data on missed opportunities for testing, the presentation of individuals to primary care services with symptoms of HIV indicator conditions and the dawning realisation of the importance of early diagnosis, the GP appeared to be gaining ground in the wider HIV health services conversation. This will be taken up further in the next chapter as interviews with members of the HIV policy network reveal the importance of this occurrence in recent HIV policy developments and discourses. Some of the tension is described by a stakeholder:

‘So I don’t think they are as bad, you know, they are generalists and I think a couple of years ago there was a great movement to put all of our care, about three years ago (2010), you know, to get GPs to look after HIV. They didn’t want it. They can’t keep up to speed with what’s happening in HIV medication etcetera. And certainly the patients didn’t want it. I mean, you know, if you’ve got anything wrong with you, you want to see a specialists and not a generalist. But I think GPs actually get bad press when they seem to serve our patients quite well and I think the other thing is, if a patient says oh, I had a really bad time, I say, well then we can change your GP.’  
(Patient representative at local HIV clinic)

Some of what is described in this quote will be further explored in Chapter 7, the discourse analysis, however, the point here is to demonstrate how central general practice was becoming in the response to HIV.

### *The economic case for the early detection of HIV*

The combined effects of a late diagnosis for HIV have economic implications. Onward transmission, greater mortality and more frequent needs for specialist health service

interventions means that late diagnosis is understood as expensive for the NHS. This was outlined in the 2008 National Guidance:

‘modelling in the US has also suggested that routine screening for HIV infection is cost effective and comparable to costs of other routinely offered screening where prevalence of HIV exceeds 0.05 per cent (12).’ (BHIVA et al., 2008: p.2)

‘The 2/1000 was extrapolated from the States because they had been a year ahead of us. Whatever they are, the CDC and Mortality and Morbidity, had done this in the states a year or 18 months ahead. They had done a cost effective risk analysis and came up with 1/1000 as the tipping point to make it worth it money wise. That’s where it came from and we adopted that. There wasn’t any other analysis to tell us where to go.’ (HIV consultant with role in professional medical associations related to HIV)

Wilson and Jungner discuss the economic rationale and the cost of testing as compared the larger medical budget as an important consideration in recommending screening approaches in principle 9 (Wilson and Jungner, 1968). At the time of guidance, evidence existed on the economic impacts of late detection but not on the cost-effectiveness of screening approaches for HIV. The RHIVA2 trial was coupled with an economic analysis in an attempt to build this evidence base.

#### ***Micro-stream 4: Socio-cultural dimensions of HIV infection***

A number of societal factors also come into the calculus enabling HIV testing as recommended in the 2008 National Guidance and enacted in RHIVA2. While these factors can be more difficult to pinpoint and clearly articulate, discourses and socio-cultural factors related to HIV infection in the UK play an important role in shaping policy possibilities. The themes described here outline some of the normative dimensions of medicine which positions treating and caring for people with HIV as a public health priority.

This micro-stream relates strongly to the ‘politics stream’ of Kingdon’s model in that it is based on data related to the tempo and general feeling of the wider population, and the political climate in relation to HIV policy (2003). This micro-stream also allows for comment on the ‘*culture*’ of HIV policy making in the UK. In regards to Wilson and Jungner’s criteria, these themes contribute to the consideration of HIV as an ‘important health

problem’, Principle 1 of the criteria, as well as feasibility and acceptability (contained in principles 2,5,6) (1968). Broad themes will be roughly summarised here, to enable their inclusion in the micro-streams, however a more nuanced discussion of these factors will follow in the next chapter.

### *HIV and ‘big P’ politics in the UK*

Sexual activity outside of marriage, male same-sex practices, multiple partnerships, the selling of sex and injection drug use, all considered risk factors for HIV, are both explicitly and implicitly discussed in UK policy documents, including in relation to HIV. Those applying for citizenship are not subject to an HIV test prior to gaining official entry, unlike in other countries with a similar global position to the UK (changed in the US in January 2010) (DOHS, 2015). The implications are that HIV policy can be developed overtly, including in relation to practices considered as societally undesirable and of equivocal legal standing (i.e. sex work and injection drug use). That HIV can be explicitly discussed within government and acknowledged as a health issue in the UK is fundamental to the development of policy related to the infection, and that HIV can occupy this space politically and within government is not a given. Kingdon’s policy stream acknowledges the politicised aspects of policy making, that HIV policy appears to have been relatively unaffected by political forces at the time of the guidance meant that while the politics stream did not appear to play a strong role in the opening of the policy window, it was an integral factor to allow other elements of the policy process to come forward, such as the policies stream. Below, a civil servant in the HIV field discusses this dimension of her work:

‘We’ve got a very supportive...it doesn’t tend to be, I think HIV and sexual health generally don’t tend to be party political. There aren’t many differences. I have worked under two...you know, the Labour administration and now the Coalition Government, and we’ve not changed our policies on sexual health. We’ve produced documents and we’ve changed the broader language. Obviously the broad structures have changed around the NHS, how healthcare generally is commissioned or delivered. But for patients, you know, yes they’ll probably see some changes down the line, but I don’t think it’s political with a big ‘p’ at all.’  
(Employee at health related government body)

### *Community resources for HIV-positive individuals*

Various organisations related to HIV and living well with an HIV infection are active across the UK<sup>7</sup>. That such services and organisations exist for patients to access, if desirable, creates a setting where outside of the medical and diagnostic aspects of HIV, policy makers are aware that there is on-going psychosocial support available for citizens. Civil society organisations regularly participate in consultations and policy development briefs and patient and public involvement in HIV research is widely encouraged and considered best practice (see Terrence Higgins Trust, National Institute of Health Research, BHIVA). While this is a less tangible aspect of policy making, this factor is present in the background of any medical changes in HIV and HIV care. The shift in pre and post-test counselling, for example, may rely on these community resources to provide psychosocial support in cases where it remains required. This important role is described by a GP with an interest in HIV:

'You can have the quickest test in the world in terms of physically doing the test but the stuff that goes around the side of the test and particularly if you get a positive result from it, is absolutely not going to be quick and I think for me, one of the kinds of payoffs of having, as you say, sort of abbreviated consent is that if someone gets a positive result there is then a very good system for picking up and dealing with that immediately so that someone isn't left high and dry with an apparently positive test and sort of chucked back out on the street again as it were.... One of the biggest issues is to make sure that that person is going to be supported after you get a positive test.' (General practitioner with a special interest in HIV and role in the development of the guidance)

### *The culture of the HIV network*

'I suppose another theme that goes through this epidemic, is courage and bravery and having to take a step into some unknown place and going 'Okay, come on then, come with me and we'll try it'. (HIV Consultant with role in professional medical associations)

Often, when the formal interviews were complete, conversation with participants would continue. Palpable in many occasions, among those working with HIV for many years, was some sense of nostalgia, triggered by recounting the transitions in HIV care throughout the interview. One participant cited how the pioneers of HIV care were beginning to pass away

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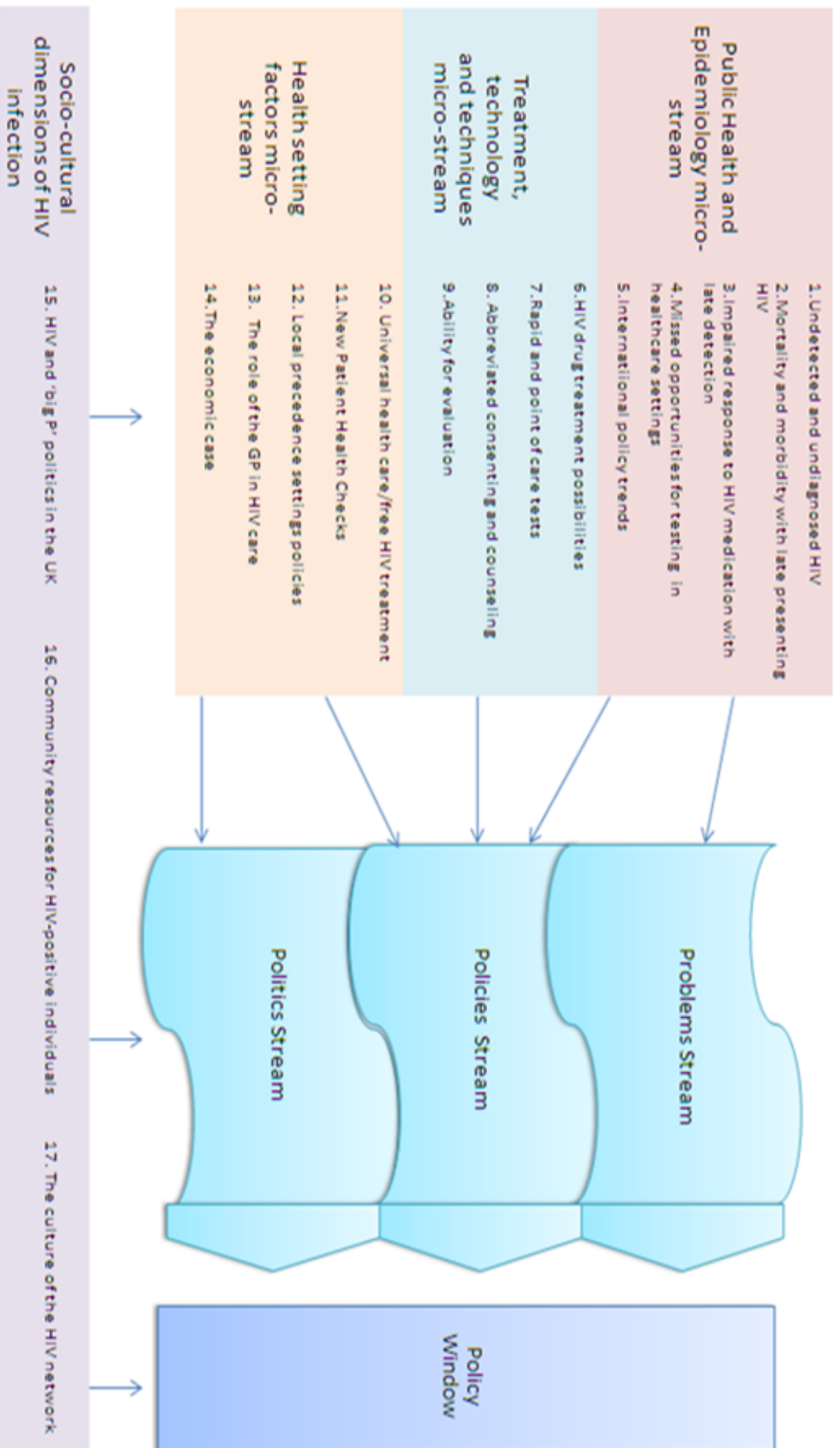
<sup>7</sup> Some predominant HIV-related community organisations include: Terrence Higgins Trust, Positive East, Positively UK, The National AIDS Trust, Gay Men Fighting AIDS, National AIDS Map, among others.



and retire. The participant remarked on the loss of important historical information that was left un-captured in the minds and hearts of these professionals as well as the loss of community felt when leaving their professions. The character of the HIV community, throughout my 10+ years of experience in the field, has appeared a passionate, dedicated and political one with a somewhat unique status amongst infection diseases or health concerns in general. Global HIV events, for example, often appear to serve as spaces for reunions amongst those working hard and with many dramatic losses and gains over years in HIV work; triumphs and tragedies of personal, political and scientific natures. At a recent event at the London School of Hygiene and Tropical Medicine on creating an archive of HIV health promotion materials, I was struck by one HIV consultant who interrupted an anthropologist's presentation on archive construction to discuss, at length, the personal archive of HIV materials he was gathering in his spare room. Thirty years of pamphlets, scientific reports, personal mementos etcetera were being systematically organised for eventual museum donation to ensure that the activism and history of clinicians in HIV was captured in medical history. This was not an anomalous occurrence. It seems a mistake not to include some discussion of the wider HIV network culture in this analysis and consider it as a factor in policy making. I developed the strong impression from my fieldwork, interviews and documentary analysis that the culture of HIV activism and its intensity attracted a particular kind of talent and mobilising force to the field and is responsible for much of the pressure leading to scientific and social progress in HIV.

Figure 4 on the following page summarises the themes related to the move towards opt-out testing approaches for HIV in primary care settings.

**Figure 4.** Summary of themes related to the promotion of opt-out HIV testing in primary care



## 6.5 Discussion

### *Key themes and the coupling of the 'problem' and 'policy' streams*

While a number of themes converged to enable the recommendation of HIV testing for new new registrants in general practice in areas highly endemic with HIV, some key themes stood out as particularly strong in enabling the policy window. The policy '*problem*' (a public matter requiring attention (Gulbrandsson and Fossum, 2009) came into sharp focus after the publication of the BHIVA mortality audit which presented strong quantitative evidence on the role of late-diagnosis in HIV-related deaths. This was cited as a turning point in the policy document as well as by members of the policy community. These data allowed for the pulling together of other related indicators (economic arguments, transmission by undiagnosed HIV-positive individuals), which when taken together made the case for a pressing policy problem.

The problem was positioned as late-presenting HIV with associated knock-on effects for individuals, population health and the economy. With this came a focus on the 'undiagnosed population' and a push to normalise testing to increase the opportunity for individuals to become aware of their HIV status. Much of what comprises the *epidemiology and public health* micro-stream relates to the defining and clarifying of this policy problem. That the problem was being defined in the form of epidemiological evidence facilitated acceptance by the biomedical HIV policy-making community regarding the existence and scope of the problem. Policy entrepreneurs (those introducing and promoting potential problems and solutions (Gulbrandsson and Fossum, 2009), were then able to pull upon much of the existing practice in HIV testing (opt-out testing, moving testing to non-traditional settings), including widely accepted and touted practices such as antenatal screening, to promote population screening style approaches for HIV testing. That existing policies of a similar nature were operating in the US, with an indicator of the necessary epidemiological picture (1/1000 in the US data) (CDC, 2006) for cost effectiveness was widely cited as precedence setting. The coupling of the epidemiological indicators, creating the policy problem, with the knowledge of successful and cost-effective existing practice elsewhere enabled the opening of a policy window between the 'problems' and 'policies' streams.

Increasing testing in general practice was positioned as a solution to the problem of late-diagnosis due to the level of contact with the general population. As the existing epidemiological data was compiled to strengthen the case of the problem, general practice (amongst other sites) was positioned as a source of untapped testing potential in HIV care and as a fertile space for encountering the ‘undiagnosed’; thereby constituting a strong actor in the policy stream.

Striking throughout the interviews was how little debate there appeared to be around the development and promotion of the 2008 National Guidance. Any tension appeared to be around ‘targeted’ versus ‘universal’ testing but even this was a difference of opinion that all agreed was unresolved until more data were made available. A dimension of likely importance to the ‘politics’ stream, and how cohesive the policy community appeared to be around this particular recommendation, is how the policy described here was in the form of guidance and it was unattached to resource in terms of funds or allocated staff and services. The policy did not come directly at the expense of other policies, but formed a part of a plethora of recommendations for increasing HIV testing. As will be discussed, most policy stakeholders interviewed felt that a multitude of approaches were required in tackling HIV and the recommendation was seen as another potential strategy in the mix. Had the policy come with allocated resource, or been promoted to the direct exclusion of other HIV services, the guidance may have become more politicised. The guidance was compiled and debated within the larger HIV policy community and received very little attention outside of this realm.

Kingdon discusses how policy windows tend to be open for a limited time due to the converging and diverging of policy streams and changes in the policy climate (2003). As a result, he argues that policy entrepreneurs generally need to act quickly to take advantage of potential policy windows (2003). Zahariadis questions this assertion, indicating that the temporality of policy windows is a little-explored area without sufficient evidence to come to a firm conclusion (Zahariadis, 2007). In the case of the policy discussed here, Kingdon’s observations appear apt. A strong theme in the interviews, unrelated to the origin of the

policy, or the factors justifying it, was the *2012 Health and Social Care Act*<sup>8</sup> and its impact on the HIV policy arena (Government of the United Kingdom, 2012). Despite the interview being about the 2008 recommendations, many participants were keen to discuss recent policy shifts. The general feel was that changes made in the *2012 Health and Social Care Act* compromised HIV care, education and testing in negative ways by fragmenting existing services and re-structuring commissioning in a way that worked against well proven approaches in health promotion for HIV. This is discussed by an HIV consultant with a policy role:

‘It’s like a Fair Isle jumper. You know, we had a Fair Isle jumper. It wasn’t perfect but we had one. Now it has unravelled completely (since the Health and Social Care Act 2012). The red wool is with one person and the blue wool is with someone else and the green wool with someone else and we are trying to produce a knitting pattern. But if you don’t want to buy the red wool, it ain’t going to be the same pattern. And it won’t fit so well or it will be a different shape, or it may be better. But those components of the whole are now sitting in different hands who don’t necessarily relate or have shared agendas yet. And HIV testing is plop in the middle of that. It is the highest risk time we have had for a long time, I feel.’

(HIV consultant with role in professional medical HIV related associations)

Many participants felt that the guidance discussed here or a further bolstering of the BHIVA guidelines or subsequent NICE clinical guidance would be impossible with the contemporary changes in the policy landscape. A strong sense of ‘we are going backwards’ was felt among most involved in the policy process and they expected to be able to identify this set-back in the epidemiological data. Rather than pushing forward with new forms of testing and screening, emphasis appeared reoriented towards maintaining what was already in place and trying to create unity in what was seen as an increasingly fragmented set of services and programmes.

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<sup>8</sup> The 2012 Health and Social Care Act ushered in large-scale changes to the organisation of HIV services. Primary Care Trusts (PCTs) were dissolved and power was re-oriented to Clinical Commissioning Groups (CCG’s), local authorities and NHS England (All Parliamentary Group on HIV and AIDS, 2013). Public health including sexual health promotion and testing was allocated to local authorities while NHS England was tasked with specialist HIV services and care (All Parliamentary Group on HIV and AIDS, 2013; Government of the United Kingdom, 2012).

## *Wilson and Jungner's principles*

Wilson and Jungner's principles for the early detection of disease as applied to the thematic analysis of the policy stakeholder interviews and principle policy document demonstrate that population screening approaches for HIV can be justified from an epidemiological point of view. The majority of the criteria for the early principles have been met and while some divergence of opinion was detected throughout the analysis, there was no outright rejection of any of the principles. The table below is colour coded to represent areas where criteria appeared to be strongly met (green) and moderately met (orange), based on the analysis undertaken in this chapter. The criteria have been narratively linked to the themes uncovered in the micro-streams and quotations.

**Table 6. Summary of findings related to Wilson and Jungner's principles for the early detection of disease (1968)**

Wilson and Jungner's Principles for the Early Detection of Disease (1968)	Linkage to themes and Micro-stream themes emerging from the policy document and interviews	Narrative linkage between themes enabling Kingdon's policy window theory (1984) and Wilson and Jungner's Principles for the early detection of disease with the data (1968)
1. The condition sought should be an important health problem	1. Undetected and undiagnosed HIV 2. Mortality and morbidity with late presenting HIV 3. Impaired response to HIV medication with late detection 5. International policy trends 14. The economic case	While HIV is widely recognised as a serious health condition in the UK due to its impact on mortality and morbidity, potential for transmission and cost to the health care system, the interviews revealed some contention regarding whether the number of people living with HIV in the UK represented a substantial enough problem to merit a screening approach.
2. There should be an accepted treatment for patients with recognised disease.	6. HIV drug treatment possibilities 10. Universal health care/ free HIV treatment	Presently effective HIV treatments are widely available, known to be efficacious and in the UK are free to individuals with HIV infection.
3. Facilities for diagnosis and treatment should be available.	10. Universal health care / free HIV treatment 11. New Patient Health Checks 13. The role of the GP in HIV care	HIV diagnosis and treatment is widely available as a part of the National Health Service. The policy explored here positions general practice as an underused site of potential diagnosis and care for HIV. Concern is frequently expressed about the ability of GP to adequately care for patients with HIV.
4. There should be a recognisable latent or early symptomatic stage.	1. Undetected and undiagnosed HIV 2. Mortality and morbidity with late presenting HIV	The natural history of HIV is well understood and significant data demonstrates that early detection and treatment significantly reduce mortality and morbidity for individuals living with the virus. HIV can be latent in the body for a significant period before becoming symptomatic.
5. There should be a suitable test or examination.	7. Rapid and point of care tests 8. Abbreviated consenting and counselling	A variety of tests are available to effectively test for HIV. These are available in general practice. While the rapid testing was used in RHIVA 2 the 2008 National Guidance policy did not stipulate which test should be used in the population screening approach.

6. The test should be acceptable to the population.	7. Rapid and point of care tests 8. Abbreviated consenting and counselling	Rapid and point of care HIV testing has been widely demonstrated to be acceptable to patients. The use of the test however in new registrant screening presents a new mode of testing with less substantial evidence of acceptability.
7. The natural history of the condition, including development from latent to declared disease should be adequately understood.	1. Undetected and undiagnosed HIV 2. Mortality and morbidity with late presenting HIV	Knowledge about HIV transmission is well understood. Knowledge on treatment options is consistently improving.
8. There should be an agreed policy on whom to treat as patients.	10. Universal health care/ free HIV treatment 11. New patient health check 13. The role of the GP in HIV care	In the case of the policy, patients registering with general practice in areas where more than 2/1000 people are living with HIV are considered eligible for the test offer. A significant theme in the data was the tension between targeting testing towards traditionally higher risk populations with a greater prevalence and between universal screening practices. This represented the largest point of contention in the data.
9. The cost of case-finding (including diagnosis and treatment) should be economically balanced in relation to possible expenditure on medical care as a whole.	14. The economic case	While earlier identification of HIV is seen as economically beneficial some concern was expressed regarding spending on HIV as compared to other blood borne infections such as Hepatitis.
10. Case-finding should be a continuing process not just a 'once and for all' project.		The intervention suggested applies to new registrants in primary care and could be considered a 'once and for all' approach. Some concern regarding this was expressed by participants as testing 'after each risk behaviour' was considered ideal though less feasible.

A thematic analysis using Kingdon's policy windows theory and Wilson and Jungner's principles for the early detection of disease have revealed important insights regarding the justification for the RHIVA2 trial. A policy window appeared due to a convergence of factors related HIV in the realms of *epidemiology and public health, treatment technology and techniques, health systems* and the *socio-cultural dimensions* of HIV infection. Analysis using Wilson and Jungner's principles for the early detection of disease reveal that screening approaches for HIV can be epidemiologically justified through broad fulfillment of the criteria and little opposition.

My analysis continues in the next chapter. I will describe key discourses related to the justification of a screening approach for HIV, which allows for a deeper exploration of the policy interviews and additional policy documents; it also assists in painting a picture of the logic of normalisation for HIV.

## **Chapter 7: SCREENING FOR A ‘NORMALISED’ HIV: A DISCOURSE ANALYSIS OF POLICY DOCUMENTS AND STAKEHOLDER INTERVIEWS**

### **7.1 Introduction**

After an in-depth description of the factors leading into the development of the guidance in Chapter 6, I now explore three discourses in operation in the UK HIV policy community between 2008-2011. Four key policy documents, including and relating to the 2008 National Guidance recommendations and the interviews with members of the related policy community are analysed with the question: What were the key discourses informing HIV testing strategies at the time of the RHIVA2 trial? Using Parker’s framework for discourse analysis, as adapted by Shaw in relation to health care policy (Shaw, 2009), I determine three key discourses justifying and upholding contemporary approaches to HIV screening in UK primary care 2008-2011. I will demonstrate how, during this period, large shifts in the conceptualisation of HIV risk, the ‘normalisation’ of HIV testing and the concept of HIV temporality and multiplicity act as important discourses influencing HIV policy in the UK.

### **7.2 Analysis**

Parker’s method of discourse analysis, as adapted by Shaw, is described in Chapter 4. The data sources used to produce these findings were outlined earlier in Part 1 in section 5.5.

For each interview and policy document a ‘thick’ document was compiled. This included a cover sheet with a summary of the document, a description of first impressions and themes when first engaging with the document including any ‘stand out’ aspects. A second sheet was appended including key terms, phrases and turns of phrase. These steps correspond with Parker’s list of questions when undertaking discourse analysis (See points 2-5 on Table 2). I then attempted to list roles and responsibilities of the discussed subjects and how this related to objects, attempting to, as suggested by Parker, ‘map the social world’. This ‘thick’ document became the core of the discourse analysis work for each piece of these data forming the corpus for analysis. Additional questions from Parker and Shaw’s guidance on discourse analysis were applied, for example what and who was promoted and upheld by the



different discourses and how do different discourses interact with one another. Acknowledging that discourses are ‘historically situated’ and that ‘discourses contain other discourses’ (Shaw, 2010; Parker, 1992) as well as support and interact with other discourses, I then dialogued my early findings with the existing literature on discourses in HIV.

My analysis of the interviews and policy documents, using Parker and Shaw’s models, demonstrated a number of discourses in operation, of which three were dominant. The first is the surveillance/risk discourse that resonates strongly with Armstrong’s discussion of ‘surveillance medicine’ and the ‘medical’ and ‘medico-moral’ discourses identified by Siedel (Armstrong, 2005; Siedel, 1993). Here, the undiagnosed sub-population of HIV-positive individuals represent contemporary HIV risk. With this shift, the general population comes under surveillance and takes on new responsibilities. Second, the HIV ‘normalisation’ discourse (Persson, 2013), which relates to the ‘HIV-exceptionalism’ discourse as posited by Smith and Whiteside (2010), was predominant throughout the policy documents and interviews. Apparent here is a tension between the ‘normalisation’ project suggested in the HIV policy documents and technologies such as population screening, with the ‘exceptionalist’ practices previously associated with HIV testing and care. New forms and practices for HIV testing come into focus and impact upon professional relationships. Third, a discourse around HIV temporality and multiplicity is also present, which relates strongly to the ‘HIV generations’ discourse first described by Newman and colleagues (Newman et al., 2010). HIV’s dynamic history and variability in regards to survivorship, biomedical expectations and practices multiplies experiences of HIV and HIV care leading to multipronged policy, fragmented policy language and challenges to professional roles. Together these discourses both inform and uphold the recommendations of testing all new registrants in general practice for HIV in highly endemic areas. I will now describe each of these discourses with reference to existing discourses in the HIV literature.

### **7.3 Findings**

#### **A discourse of surveillance and risk**

‘The strangest thing is people don’t often see themselves in a high-risk group. Everybody’s in a high-risk group nowadays.’ (Patient representative at specialist HIV clinic)

The push to be aware of one's HIV status and to increase testing in the UK population at large is directly related to the changing biomedical context of HIV treatment. HIV-positive individuals who access and adhere to drug therapies, achieving an undetectable viral load, have little chance of transmitting HIV, yet remain HIV-positive. This transformation of the HIV-positive body from one of risk and disease to one of relative safety and health inspires a shift in how HIV risk is presented and understood. David Armstrong's description of surveillance medicine discusses transitions in illness and health and how these changes alter conceptualisations of risk:

'The techniques of health promotion recognise that health no longer exists in a strict binary relationship to illness, rather health and illness belong to an ordinal scale in which the healthy can become healthier, and health can co-exist with illness; there is now nothing incongruous in having cancer yet believing oneself to be essentially healthy (Kagawa-Singer 1993).' (Armstrong 1995: p.400)

He outlines surveillance medicine as operating around three themes: a problematisation of normality, a redrawing of the relationship between symptom, sign and illness, and the localisation of illness outside the corporal space of the body (Armstrong, 1995). Within this logic, illness becomes something with endless potential and always in waiting. One may begin to survey oneself and question one's state of health and normality, alert to risk factors and signs and symptoms of illness in development, an activity encouraged by the 'know your status' messaging of HIV campaigns (Banda, 2014). Screening activities, such as the RHIVA2 trial, adhere to this logic, attempting to direct and interrupt the anticipated march of illness from early possible indicator to full blown disease.

### *The undiagnosed as the new risk site for HIV*

The surveillance/risk discourse problematises the unknown and presents this lack of knowledge as a threat to the individual and society. Here, this manifests as emphasis on the 'undiagnosed' HIV-positive population. This oft-referred-to category of individuals are an important imaginary in HIV; as future patients, as the promised deliverable of HIV policy, as victims, as embodied risk and as a pesky elusive goal representing a final challenge in controlling the UK epidemic. With a large percentage of the HIV-positive population in the UK being undiagnosed, the untested population at large becomes the new site of HIV risk. This shift is described by an HIV consultant in the quote below:

‘The biomedical activism is now around testing in a very focused way. The burden of responsibility, the messages that are going out. In the old days the person who was tested and was positive was somehow the victim and was somehow responsible and took blame. Now the message is the untested person who is the potential victim because they don’t know. And so your social responsibility, your herd responsibility as an individual, has suddenly come into sharp focus I think. A lot of the social media stuff now is ‘Would you rather have sex with someone who has never had a test?’ Actually the former is considered to be at lower risk, which means there is something now about both clinicians, practitioners and the general population about some burden of responsibility being put on the untested.’ (HIV Consultant, Departmental head and senior position in a professional medical association)

It is estimated that the majority of HIV transmission in the UK is by those unaware of their status, a category anticipated to grow as biomedical practice moves towards the earlier prescribing of ARVs to HIV-positive individuals, regardless of their CD4 count (presently an important indicator of when to begin treatment) (HPA, 2011; BHIVA et al., 2008; NICE, 2011a; NICE, 2011b). With this comes the wide-scale achievement of an undetectable viral load among HIV-positive individuals adhering to medication, and therefore little to no transmission.

There has been a push to learn more about ‘the undiagnosed’ in the HIV policy field. The seemingly wholesale support for testing raises interesting questions around those who do not accept or seek out tests and the persistent category of undiagnosed HIV-positive individuals. The opacity of ‘the undiagnosed’ is presented as an obvious challenge in the documents reviewed and interviews undertaken. A GP with a special interest in HIV describes this tension below:

‘you have to do bundle testing otherwise, you know, how can you pick up the ones who you don’t see? And, you know, that population might actually be very different than the ones who actually come and see you. And so, you know, are you potentially causing a problem with equity when you only test people that you see and you don’t test the people that you don’t see...you only see who you see. And in order for any screening program to work you have to look at the population. And yeah, it’s difficult to screen anyone who might not be at risk, but you know, at least they get asked.’ (GP with special interest in HIV and participation in professional medical associations)

### *Surveillance of the general population*

‘If you tested everybody in the country, mandatory, there would be no undiagnosed. There would be no more late diagnosis. We could sort the problem straight away.’  
(Employee at local HIV-positive patient organisation and member of local health organisation)

‘Surveillance medicine requires the dissolution of the distinct clinical categories of healthy and ill as it attempts to bring everyone within its network of visibility.’  
(Armstrong 1995: p.395)

The reorientation of risk as ignorance of one’s HIV status centralises individual risk-behaviour on the one hand, and population-based approaches, such as the universal offer of testing, on the other. It works to bring the general population into view and under the surveillance of public health infrastructure. Settings such as primary care come into focus. The population is informed that knowledge of their HIV status is protective of their health. According to HIV specialists, techniques such as home and rapid testing mean it is ‘easier than ever’ to access a test. Outreach means individuals are tested in a variety of settings, such as pubs and churches along with seemingly unrelated health settings such as dermatology and colposcopy clinics, for example. The emphasis on ‘tracking down’ HIV-positive individuals is described by a patient representative in the quote below:

‘We need a “it’s better to know” campaign really, you know kind of which would take huge pressure I think off GPs. My GP who has people in tears, it could help educate people to look for the effects, you know, the potential signs of HIV pneumonia, TB, you know what I mean? Or you know, a whole range of things, yeah, and we could track down those 30,000 people who don’t know that they’ve got HIV who are going around spreading the virus.’ (Patient representative at HIV specialist clinic)

Regardless of this apparent easy access to testing, one would imagine it is difficult to always be aware of one’s status, and while it is suggested that individuals test after every ‘risk behaviour’, determining when one has truly been at risk of HIV infection can be difficult, inconvenient or undesirable. Analysis of the discourses around the untested population assumes the objectives of the citizen to be their health and the health of the population, with health defined in narrow terms. Based on biomedical rationality alone, we might expect individuals to want to learn their HIV status and to then, if positive, adhere to medications indefinitely. While for some patients this may be the case, this assumed linear progression

ignores the complex psychosocial factors related to HIV infection which may not, and indeed, historically have not, always lead individuals to make choices around HIV that speak to particular biomedical rationalities alone. Here the medical and medico-moral discourses (Siedel, 1993) also become apparent, as individuals are imbued with a responsibility to monitor their HIV status for the good of the population.

### **A discourse of ‘normalisation’**

‘I would suggest that in primary care the person coming in with an ingrown toenail is not thinking about a life changing diagnosis’ (HIV consultant with role in professional medical associations)

The ‘normalisation’ of HIV testing was an explicit objective in the policy documents analysed. Despite this, normalisation appeared as an unsettled discourse, relating to tension with the ‘HIV exceptionalism’ discourse (Smith and Whiteside, 2010) and in some senses the ‘rights’ and ‘activist’ discourses (Siedel, 1993), which have long been in operation in the HIV field. The ‘HIV exceptionalism’ discourse, which describes the ways in which the approach and techniques, as well as the large attention, funding and action HIV garnered internationally are comparatively exceptional in the realm of infectious disease. Smith and Whiteside, quoting Lazzarani, describe the discourse:

‘Descriptively, exceptionalism posited that in the early years of the HIV epidemic, HIV was considered so different, so ‘exceptional’ in comparison to other communicable diseases that advocates and public health officials agreed that HIV policy should cater to the uniqueness of the epidemic rather than treat it like all other communicable diseases. Supposedly, the argument goes, public fear was so great, the political power of gay men so substantial, and concern over stigmatization so real, that public health authorities abandoned ‘traditional’ approaches to communicable disease control in favour of a civil liberties approach [9].’ (Smith and Whiteside quoting Lazzarani 2010: p.2).

The ‘HIV exceptionalism’ discourse is informed by the rights and activist discourses, identified by Siedel as well as Smith and Whiteside (Siedel, 1993; Smith and Whiteside, 2010). Patient and public networks, calling upon the human rights framework to support access to HIV therapies and reduce stigma towards HIV-positive populations, largely drove these discourses. Both were strongly influenced by international perceptions of HIV and were largely born through the struggles in acquiring affordable treatment for individuals in

less developed countries (Smith and Whiteside, 2010). Arising largely in response to the medical and medico-moral discourses (Siedel, 1993), the rights and activist discourses centralise the patient as a person deserving of rights and highlight the societal, psychological, economic and gender-based aspects of HIV infection. Smith and Whiteside describe some of HIV's historic exceptionalism in the quote below:

‘During the 1980s public health adopted a human rights framework that took societal-based vulnerability into consideration and increasingly became involved in societal transformation efforts [5]. HIV/AIDS was positioned not only as a health condition, but also as a social issue that required a political, as well as medical, response [4]. The scientific establishment's control on public health was challenged, and a new type of public health initiative was called for: one that provided counselling, protected privacy, and empowered the patient’ (Smith and Whiteside 2010: p.2)

Emphasis on privacy and confidentiality, counselling and psychological services and a social movement to ensure access to high-level treatment and care are seen as the legacies of these mobilisations and discourses (Smith and Whiteside, 2010). In the case of the corpus explored here, the rights and medical discourses often appeared merged, appearing as a sort of public health discourse of biomedical rights, an observation also noted by others in the literature (Parkhurst, 2012).

The related normalisation discourse contains, challenges and colludes with aspects of the exceptionalism and rights/activist discourses. In recent years, “HIV exceptionalism’ has been challenged (Mazanderani, 2015; Persson et al., 2014; McGrath et al., 2014; Mattes, 2014). Much of what was seen to inspire the exceptionalism, at least in high resources settings, is thought to have been overcome with changes in technologies and treatments for HIV, which have altered the clinical picture and also strongly impacted survivorship. In response, a discourse of ‘normalisation’ has appeared. Within this discourse ‘biomedicine’ is arising as a synergistic agent of protection and normalisation, promising to turn people with HIV “into regular, unremarkable citizens, just like anyone else” (Squire, 2010: p.407)’ (Persson et al., 2014: p.1066). Throughout the interviews, many participants spoke freely about the normalisation of HIV testing, however HIV infection itself as ‘normal’ was often discussed with caveats. This reflects a trend in the literature. The transition of HIV from a ‘plague’ model of illness (Beaudin and Chambre, 1996: p.684; McGrath et al., 2014) to a chronic disease has been discussed since soon after the emergence of anti-retroviral therapies, which

began to significantly increase the life course of HIV-positive individuals from the early 1990's (McGrath et al., 2014). The discourse on normalisation has appeared to gain prominence since the groundbreaking findings of the Swiss HIV Cohort study in the early 2000's and the defining HPTN 052 study of 2011 which established the role of ARVs in rendering HIV virtually non-infectious with appropriate adherence (Vernazza et al., 2000; Cohen et al., 2011). The emergence of the undetectable viral load and the HIV-positive body as potentially non-infectious has made what was a nascent discourse on normalisation an entrenched discourse in the HIV field in recent years (Mazanderani, 2015; Persson, 2013; Persson et al., 2014; McGrath et al., 2014; Mattes, 2014). A swell of critiques have emerged in response, and while they may be critical of the historical exceptionalism surrounding HIV as well as the normalisation discourse, they tend to call for a continued form of exceptionalism largely due to the impact of HIV infection on the social reality of individuals and its status as a quintessentially 'biosocial' infection (Persson et al., 2014: p.1088).

These critiques emphasise the impact of a HIV diagnosis on identity and relationships, and the burden of medication and the everyday management of the illness on dimensions such as socio-economics and feelings of safety (McGrath et al., 2014; Mazanderani, 2015; Persson, 2013; Persson et al., 2014; Moyer and Hardon, 2014; Mattes, 2014; Philbin, 2014). These authors would argue that a potentially sexually infectious condition with such a long-standing social stigma, with direct impacts on intimate relationships, and an ongoing dependency on health care services and biomedical relationships, struggles to fit into a categorisation of 'normality' (McGrath et al., 2014; Persson, 2013; Persson et al., 2014; Mazanderani, 2015). The socio-economic dimensions of an emphasis on and prioritising of one's health so as to ensure drug therapies are optimised, they argue, tend to be overlooked. Recognising, according to this literature, that individuals with HIV who have better and more access to material resources, a more stable everyday life or more inclusive and accepting communities of support will have a differential ability to 'live well' with HIV is critical. For example, McGrath et al. as well as Kalofonos found that food prices directly impacted individuals' sense and ability of managing their HIV well (McGrath et al., 2014; Kalofonos, 2010). Even when treatment may be freely supplied and health services equally offered to the general population, such as in the UK, other socioeconomic, psychosocial and contextual factors impact upon HIV infection and an individual's response to treatment.

### *Normalisation and primary care*

The tension between HIV's historic exceptionalism and the more recent normalisation project was evident in the policy documents and the accounts of those active in the wider policy community. From this flowed many implications for practice and for the primary care setting. The 'normalisation' of HIV testing was positioned as a way of reaching the undiagnosed population and ensuring citizens were aware of their HIV status. Normalisation as an objective was stated within the policy documents and was supported with a variety of language in less direct ways throughout the documents ('as with any other medical investigation' (BHIVA et al., 2008: p.10) 'like in usual medical practice' (HPA, 2011). See these quotes from the policy documents:

'PHIAC considered that the routine offer and recommendation of an HIV test in certain settings would go some way towards normalising HIV testing.' (NICE 2011a: p.17)

'Historically, HIV testing has been associated with genitourinary medicine and sexual health settings. PHIAC recognized that if other healthcare and community and non-clinical settings were used for HIV testing this would help make such tests the norm.' (NICE 2011a: p.18)

As seen by the policy maker and HIV expert speaking in the quote below, the term 'normalisation' is often used with caveats, which I believe reflects the nuance and attention to patient experience emphasised by the rights discourse and an unsettled tension between an 'exceptional' or 'normal' status for HIV infection. This careful way of speaking about HIV and those impacted by the infection is a strong theme throughout all interviews and policy documents, a dimension I will further discuss later in the chapter. This continues to be evident in the quote below:

'I mean, we talk about universal testing, we talk about normalising testing which is probably an inadequate use of normalise obviously when you test for HIV it's not normal.' (Public health consultant with a research role and position with national health organisations)

The changes called for through the normalising of HIV testing posed a number of challenges in practice, stemming from the history of HIV exceptionalism and in some senses the unresolved merging of new and old practices surrounding HIV. This was evidenced in three ways throughout the interviews and policy documents: by bringing new forms and sites for



HIV testing into focus, by centralising general practice in the response to HIV and by challenging prior best practice in HIV testing and care.

*Bringing new forms, sites and practices of HIV testing into focus*

‘So we need to address testing. There are a number of ways of doing that. That is how do we get testing more prevalent, how do we encourage people for testing... So I mean there is that one about community testing which we have a very mixed view on. You know, do you really want to be told that you are HIV-positive while you are sitting in the pub one evening? Because they do testing in pubs. Who wants to receive their cancer diagnosis sitting in a pub?’ (Head of HIV-positive patient organisation)

The HIV normalisation discourse brings new sites and methods of testing into focus, for example rapid tests. In emphasising the normality of testing for HIV infection, spaces where tests are offered expand. Providing testing as a part of one’s overall health check within general practice is a relatively new mode of offering testing. Other important sites within the policy document were ‘community’ spaces. This includes churches and community centres, among others. Such sites were often those where the ‘undiagnosed’ might be encountered. Along with recommendations for screening style approaches in primary care were guidelines for testing in other ‘non-traditional’ clinical settings. The HINTS (HIV Testing in Non-Traditional Settings) study was also underway at the time of the RHIVA2 trial. This study assessed the acceptability and feasibility of testing in emergency, acute care, dermatology and primary care settings (Rayment et al., 2012). In April 2014, home testing was approved in the UK and HIV tests are now available for purchase at local pharmacies (Stephens, 2014). Rapid testing and what it brings forth is discussed by a GP in the quote below:

‘So the rapid test brings- it’s a cluster isn’t it? A rapid test? So it means you get results quickly. It also means it’s been linked with healthcare assistants. So it suddenly means a different person is doing the test as well... and so by implication, ’cause this is task shifting then by implication, you know is a health care assistant qualified to do any sophisticated chats? So therefore, we’re now by default dumping the counselling... there is a constellation of things kind of going on here isn’t there?’ (GP with special interest in HIV and participation in HIV related medical associations)

In this case, offering tests as a part of new patient health checks represents a change to a number of the practices that were previously thought to exceptionalise HIV. These may include consent procedures, pre and post-test counselling and care in specialist clinics. Once hard-won dimensions of HIV care, such practices are now positioned as barriers to testing and as contributors to stigma surrounding HIV tests. An HIV consultant describes how this tension plays out in the clinic:

‘The complication we have got now is that it is all muddled up. So half the medical/clinical workforce have to do counselling and you are going ‘Well you have’ ‘Oh yeah yeah, because I went on a course in 1992 and I know that you have to do counselling.’ Then you have the bright young things coming out of medical school who look at you as if you are mad.’ (HIV consultant with role in professional medical associations)

Changing professional understandings of best practice for HIV are further discussed later in the chapter.

*The growing role of general practice: ‘Thinking HIV’*

‘I think testing is still the biggest issue for general practice. I think that there’s still a lot of work to be done on getting routine HIV testing for certain clinical presentations. I think that there are still issues about the opportunistic testing of people who are at risk and there are some issues around how you identify those in general practice so, you know, it is difficult in general practice to have a way of identifying say a man who has sex with men because at the moment we can only code that as an illness in our systems and clearly that’s unacceptable to do that so there is no- so you can record it in someone’s record but then as time goes it cause falls into the background because it’s just a written thing in there, you know...so there are still issues, not only issues about practices making it somewhere where people feel it’s acceptable to identify themselves as say MSM or someone who’s used drugs, but then also about how that’s recorded in a way that can be clinically useful and then there is that next step of actually offering HIV testing in those circumstances.’ (GP with special interest in HIV and involvement in the 2008 guidance)

Primary care occupied an interesting space in the discourse on normalisation. Across the board in the interviews and policy documents, primary care was positioned as an opportunity and as an underperformer in HIV care. The data on missed opportunities for testing along with the changes in the technology, techniques and treatment landscapes (as discussed in the previous chapter) brought the general practice into focus as an untapped source of HIV

testing potential and an important site in the ‘normalisation’ logic. All manner of health professionals are now able to offer tests and patients with stable HIV infections should be seeing their GP for health concerns unrelated to HIV at a seemingly cheaper cost to the NHS. What emerged in the interviews however was wide-scale support for the ‘normalisation’ of HIV and HIV testing, but also inter-professional tensions affected by the legacy of ‘HIV exceptionalism’ and to some degree its related ‘activist’ discourse. Of additional frustration for GPs was the clash between the pragmatic dimensions of primary care and the exceptional practices of historic HIV care. This tension often played out around targeted versus universal testing and its feasibility in a primary care setting. Some GPs considered the ‘exceptional’ status of HIV amongst infectious diseases affecting the general population as a challenge to their sense of an appropriate dedication of resources. This is described in the quote below, with reference to resource splitting:

‘And then what are we saying, you know, about Hepatitis screening. I can’t do that. There’s far more people dying, getting their liver cancers and their liver failure from viral Hepatitis frankly. And in all honesty, the figures make HIV in the UK, you know..., and you just want to laugh sometimes, you know? Like I can’t as a GP single out HIV for this special treatment in the London setting, you know? Hepatitis is, we should be spending far more time and energy on Hepatitis.’ (GP with special interest in HIV and participant in HIV related medical associations)

Typically, HIV-positive patients in the UK have been cared for in specialist secondary care services. The expert knowledge around HIV treatment options, the virus itself and the psycho-social dimensions of the infection could all be tackled in such centres, which typically house specialist HIV consultants, health advisors, psychologists, research nurses and patient representatives, amongst others. It appears that inter-professional tensions around best practice for HIV-positive individuals has contributed to the problematic way HIV in primary care has been positioned. While it is difficult to determine how evidence based many of the ‘vague swirling fears’ (GP with specialisation in HIV, member of professional medical association) surrounding general practice may be, what is relevant here is their interaction with existing discourses in HIV and how they impact the policy agenda. Cited problems in primary care tend to include issues of confidentiality, drug contraindications, stigma, missed opportunities for testing and in the words of one of my patient representatives for this project, being ‘HIV unfriendly’. A GP describes this legacy:

‘[there are] lots of historical influences, and lots of kind of slight vague, swirling fears about confidentiality and discrimination in choosing not to use their general practice. So, I felt we were kind of in a vicious circle whereby if GPs weren’t seeing people for HIV they weren’t ‘thinking HIV’ and therefore they were less likely to think about testing people for it.’ (GP with specialism in HIV and participation in professional medical association)

Interviewees with experience of primary care discussed the occasional clash between suggested practices emerging from the expert HIV community with the structures of primary care. Primary care appeared assigned with a number of recommendations but little resource or consideration of existing structures. Resource was continually mentioned, along with the growing load of responsibility placed on general practice to incorporate complex health care needs in a streamlined fashion. The quote below reveals some of the frustration along with the pragmatic dimensions of delivering generalist medical service:

‘But they don’t understand how general practice works and they don’t understand oh, you know, I mean this comes back from...there is still a whiff of it that specialists think that in their area of expertise they have clinical governance, leadership and responsibilities over what happens in general practice as opposed to lying within general practice. So I’d say so does that mean that the patient I see in the first minutes, if their consultation was about diabetes, that the person responsible for my quality of care is the local endocrinologist? And then the second part of my consultation is about renal problems or HIV and then suddenly the clinical governances in that part of the consultation is the responsibility of? You know, it is just nonsense. General practice has its own professional structures and responsibilities and there is an idea that, you know, we cook up something that’s meant to be good and you’re all meant to be doing and actually it’s my responsibility to get you doing it and it’s fine.’ (GP with special interest in HIV and membership on professional medical associations)

As primary care became centralised in the response to HIV the tensions between the exceptionalism and normalisation discourses played out in real terms by challenging existing structures and practices. Primary care was assigned new roles and the changing nature of HIV infection and the multiple practices surrounding it transitioned. What were also present within these discourses however were the temporal dimensions of HIV and its care over the course of the epidemic; a discourse in its own right.

## **A discourse of HIV temporality and multiplicity**

Throughout the PhD, I have come across points of tension when considering HIV contemporarily. One has been related to the infection's transition into a chronic treatable medical condition and the subsequent effects. This initially struck me as a challenge for health promotion, where on the one hand the message has been: 'do not get HIV, it is dangerous to you and your partners, you might die' and on the other hand: 'HIV is a treatable medical condition, you can live well and for a long time and be unlikely to transmit the infection by taking medications'. The tension appears to be around how one can be both healthy and ill while having an HIV infection, how the infection can be both 'chronic' and 'acute' within one body, and how testing can be normal or dramatic depending on the stage of the infection and situated factors. Temporal dimensions appear important within the infection for a single person (i.e. early/late detection), yet considering HIV historically also reveals how diverse HIV has been in its social and clinical enactments. One could begin to consider that there has been a multiplicity of HIVs (Mol, 2002). Essentially, pulling HIV and HIV infection into a unifying definition or summary of descriptions and experiences has become more difficult as the treatment possibilities, ways of managing the infection clinically and negotiations of 'survivorship' have diversified (or possibly just been made known to official bodies) (Newman et al., 2010). Considering HIV temporally and multiply allows for a description of the findings around the varied history of HIV testing practices, multipronged policy approaches and unsettled policy language as well as the alterations in professional relationships surrounding HIV infection.

This discourse presents challenges for policy and is reflected in the suggested 'multipronged' approach to health promotion and HIV testing activities, a strong theme throughout all four policy documents and most interviews. This has also meant that different providers and patients may have had widely variable training and experiences around HIV infection.

Newman et al. identified the discourse of 'HIV generations' in their paper: '*HIV Generations? Generational discourse in interviews with Australian general practitioners and their HIV-positive gay male patients*' (2010). While the primary objective of their study was depression, it became evident throughout the interviews that a pre and post-HAART HIV

experience was impacting the meaning of HIV for patients and practitioners. The generational discourse is defined through the three main features of ‘treatment histories’, ‘socioeconomic status’ and ‘modes of survivorship’: Newman describes the discourse below:

‘A pre-HAART generation is imagined as burdened by the limited availability, effectiveness and side effects of early treatments. Their socioeconomic lives are seen as shaped by an inability to sustain employment, leading to entrenched disadvantage. The surprise renewal of a long-term life course means this pre-HAART generation is now represented as dealing with ‘survivorship’ issues relating to body image, community and family support, and social status. The post- HAART generation, on the other hand, is imagined with far less clarity (particularly by the GPs), perhaps because there are such a diversity of issues that affect PLHIV now, whether they were diagnosed pre- or post-HAART. However, in so much as a ‘picture’ of post-HAART generation is being painted here, it could be best characterized by a more individualized experience of health and illness, a greater focus on the challenges of balancing work and health priorities, and complex new social and survivorship issues relating to sexual ethics, community and responsibility.’ (Newman et al. 2010: p.1726)

While Newman et al.’s description of HIV generations is fairly specific to patient experiences with some reflection on impacts for general practitioners, it highlights important temporal and historical aspects of HIV as they relate to broader changes in HIV treatment possibilities but also the stage and treatment of HIV infection within individuals alone.

### *HIV testing’s varied history*

‘We used to make it so difficult to take a test in the old days, you used to have to be a PhD just to propose it.’ (Patient representative at local HIV specialist clinic)

A look at the varied history of HIV testing helps articulate the temporal shifts in HIV testing as well as shed lights on the current enthusiasm for universal HIV testing. Transitions in the professional community around approaches to testing are well summarised by an HIV consultant with a senior position in a HIV related professional medical association. She describes her work in HIV since the early days of the epidemic:

‘If we go back to the very beginning when we didn’t know HIV was causing AIDS and there wasn’t a test, the way the subject of testing was approached was very different. We then got a test but without treatment. That put people into a really

complicated place because the issue was then if you test, what difference will it make? In those early years of the epidemic not only did it make little difference to your own future, it potentially made things a great deal worse. So there was a really difficult moment about what you do with this new test we've got.' (HIV consultant, departmental head with senior position in national medical organization)

The consultant goes on to discuss the relevance of changes in the treatment possibilities to the experience of offering testing. She then puts the zeal of the HIV community to endorse and promote testing into context:

'It became clear that AZT on its own was buying something... so suddenly, or not even suddenly, the thrust of our testing grew because there as an intervention that made sense. That was quite an important tipping point because at that point there was enough experience of nothingness, no follow up, for this to be quite a strong event. And so moving forward into testing became quite complex and it took quite a lot of influencing around health professionals because the mantra had been, you don't do that. Suddenly, we were saying 'you know what, you do do that!' That has only grown as treatment has improved. And so as we have got to the point that treatment is now as good as it is in securing longevity and preventing death then of course something that is in the hands of biomedical practitioners, that you are able to do that with, you want to do it. And so now the expert medical community really can't test enough people.' (HIV consultant, departmental head with senior position in national medical organization)

The social and biomedical mobilisations of the research community around HIV have long appeared as fast-paced, dynamic and impassioned, with HIV taking on a unique status among communicable disease, particularly sexually transmitted infections. With a number of committed health practitioners long witnessing the suffering of their patients, now armed with the treatment possibilities available in the UK, the contemporary HIV testing context and the support for policies around early detection and population wide testing become more understandable.

#### *How 'multiplicity' plays for policy and unsettled policy language*

This diverse character of the infection and its various presentations can also be mobilised in multiple ways to support policy objectives and interests. In regards to the policy in question, offering HIV tests to all new registrants in general practice in areas highly endemic of HIV, multiple aspects of HIV infection can be called upon to justify and uphold the policy. HIV as both clinically chronic and acute or as socially normalised and stigmatised can play in

support of policy objectives. One logic would go: if HIV is a chronic, treatable medical condition, then it should be normalised as a part of regular health checks and it is acceptable to be offering tests to everyone with little pre or post-test counselling with reduced time and resource allocation. Another might be: if HIV is a life threatening, infectious disease with serious impacts on population health and resource, then new ways of detecting and diagnosing the condition are justified, supported by a danger and risk discourse, as discussed earlier in the chapter. While both statements are evidentially supportable it means that various, sometimes competing, other times colluding, discourses can be mobilised to support the policy in question, which may impact its widespread support, along with the enabling of a policy window, as discussed in Chapter 6.

Another tension appeared in the policy documents between generalising HIV infection or communities affected by HIV, while also attempting to discuss broad strategies and populations. In the NICE guidance on testing black African communities for example, a list appears defining ‘additional identities’ black Africans may have. See this quote from the guidance:

‘Throughout the guidance the term ‘black African’ includes anyone who identifies themselves as black African, whether they are migrants from Africa, African descendants or African nationals. Black African communities encompass diverse population groups including people:

- from a range of cultural, ethnic and faith backgrounds
- who may be heterosexual, bisexual or homosexual
- who may have physical or learning disabilities
- whose knowledge or understanding of English may be limited’

(NICE 2011a: p.4)

This stood out in my analysis as incorporating aspects of the ‘rights’ and ‘activist’ discourse, and recognising the range of ways HIV interacts with populations, but also as a struggle to sensitively speak about populations in a generalised way. It appears that even the policy documents struggle to acknowledge the situated, individualised aspects of HIV infection while making population-based recommendations.

*Impacts on practices and relations*



‘there was this whole sub-profession of counsellors built up around it frankly. There were a whole load of specialists who were grabbing and white knuckling patients. This is me being very cynical now. Some of my best friends are HIV specialists but there was a keep off our precious territory thing going on for ages, right? (GP with specialism in HIV and participation in HIV professional associations)

The generational shifts in both the nature of HIV infection and the culture of practices surrounding the infection were also evident when discussing the expanding role of primary care and the role of HIV practitioners. One young HIV consultant felt that there were strong differences between her generation of specialist consultants and the older providers who treated HIV in the pre-HAART era. She felt that while primary care received much of the blame for not better incorporating HIV care, there were aspects on the side of expert consultants that impacted this impression. See this quote:

‘There are still a few kind of stalwart absolutely not. I will never see my GP for anything. I want you to manage my HIV care. But I think it’s just about how we spin it with people. So, you know. I can pinpoint the clinicians that work within my unit, whose patient they are because they will be the clinician having negative impression about primary care that’s led the patient to believe that, do you know what I mean? A session with a different doctor would perhaps put a different slant on it for me.’  
(HIV consultant with membership on HIV related professional medical associations)

Present here are also the ‘rights’ and ‘activist’ discourse (Siedel, 1993). Throughout the interviews it was clear how much care and nuance are valorised in discussing the infection and the patient population in relation to HIV. As aforementioned, a great many of the older HIV specialists have been treating HIV since it was a deadly condition for which they could provide little more than therapeutic and palliative care. Some have journeyed through the transitions of the infection and its implications alongside their long-standing patients. The early years of the HIV epidemic were often cloaked in war terminology. The language around the ‘fight against AIDS’ has now transformed (‘the response to HIV infection’ (NAPWHA, 2013) and it is feasible to imagine that early practitioners felt and may continue to feel engaged in an epic battle for lives and against social injustices. The young consultant continued, as was echoed in a quote earlier by a specialist GP, about the sense of territoriality this may have engendered:

‘I think that HIV practitioners have been quite guilty of closeting their patients and sort of keeping them all in house and making them feel like we can manage all aspects of their healthcare better than primary care physicians or whatever so we have kind of fostered this attitude amongst patients as well that HIV is not accepted by the wider community’ (HIV consultant with membership on HIV related professional medical associations)

The consultant highlights some of the generational differences in HIV care and experience, describing some of the territoriality that may have ensued and its impact on the perceptions of patients.

#### **7.4 Discussion**

Through analysis of three dominant discourses HIV appears as an active and changing entity as it interacts with science and society. Language, practices and locations for HIV have diversified in the face of a disease in transition and it becomes apparent that practitioners have been treating different HIVs dependent upon the site, the timing and the individual (amongst other variables). HIV discourses are mobilised in different ways and alter material practices.

HIV screening activities such as those seen in RHIVA2 are centralised and upheld by discourses of risk and surveillance, HIV normalisation and of HIV generations. These discourses interact, challenge and inform each other.

Positioning undiagnosed HIV and therefore ‘healthy’ civilian bodies as sites of danger and risk represents shifts in how risky bodies in relation to HIV are conceptualised, particularly as those known to be HIV-positive begin to gain new claims on health and lose their ‘infectious’ status. As a result, activities such as population wide screening bring the general population into view and encourage individuals to survey their own bodies and behaviours for signs of potential infection and illness in waiting. Practices shift to streamline HIV testing activities with knock on effects for professional roles and responsibilities. The tension between being healthy and normal with HIV infection, while still recognising the exceptional circumstances being HIV-positive brings into being, represents a strong tension in the discourse, but also a tension lived in material practices. General practice becomes a central site for HIV testing

and a potential space for greater HIV care. This challenges historic best practice and professional identities. The multiplying of known experiences around HIV, the temporal dimensions of the illness within individuals and over the history of infection and this relationship to practices and providers means that HIV has been enacted in multiple ways over diverse spaces and times.

One way of integrating these findings is by thinking of HIV as multiple, as suggested by Annemarie Mol in her praxiography of disease, *The Body Multiple* (2002). In this suggested ontology, disease may be seen as ‘more than one but less than many’ dependent on situated factors. Instead of imagining one singular HIV sitting in various sites and individuals and undergoing diverse practices, Mol may suggest that there are many HIVs, constituted by these factors, not only subjected to them (2002).

Thinking of HIV as an emergent and multiple object, as suggested by Mol, allows for the consideration of how HIV has been presented in the policy documents and interviews more fully and may allow for the accounting of the infection’s diversity in a way that can neutralise tensions and let policy, providers and settings adapt without encountering such degrees of dissonance. The fragmented policy language becomes more understandable, as do the multipronged policy approaches. In this frame, HIV as both normal and exceptional, the HIV of yesterday’s specialists and of the new ‘bright young’ medical students coheres. This way of thinking about disease may be more helpful than struggling to bring HIV into one unifying definition as space for multiplicity is created and a reconciliation of descriptions and definitions becomes less necessary.

These themes will be considered throughout the thesis and more centrally in Part 3 where patient experiences in RHIVA2 are explored. As I describe the enactment of the RHIVA2 trial, the patient experience of testing and the work on the pragmatic trial design it is possible to trace the influence of these key discourses, including their role in constituting the two logics, or stories, threaded through the thesis.

## 7.5 Conclusion to Part 1

The discourse analysis presented above in Chapter 7, combined with the empirical analysis in Chapter 6, introduce what constitutes Story 1 of this thesis. The logic of normalisation becomes evident and ushers in new populations for testing and sites such as general practice take on increased responsibilities in HIV care.

‘Normalising’ HIV came about in response to HIV’s historic exceptionalism and aims to treat HIV ‘like any other medical condition’. This logic reflects shifts and tensions in transforming understandings of health and illness and in practices related to detection and diagnosis. Here, the normalisation of HIV is aspiring and aims to reorganise perceptions, practices and experiences of the infection to align them with biomedical shifts in the implications of the disease on the body. Shifts positioned as available and desirable if one adheres to HIV medication and participates in medical services. Screening, once considered an inappropriate method of testing for HIV is enabled by this move and informed by HIV’s biomedical transformation into a treatable condition. As a ‘normalising technology’ (Philbin, 2014) screening for HIV in primary care represents a new mode of testing and aims to detect an ‘abnormality’ that enables medical intervention. Such intervention may translate into survival for an individual and the potential to access to a ‘normal’ life while remaining categorically ill.

## **PART 2: RHIVA2 in practice: Implementing and evaluating a complex intervention**

In Part 2, I explore the implementation of the RHIVA2 trial across a sample of primary care organisations. It is here that ‘logic of normalisation’ and the ‘logic of the pragmatic trial’ converge in practice. In RHIVA2 20 GP surgeries in a borough with a high prevalence for HIV were tasked with implementing the policy described in Part 1, the offer of an HIV test to new registrants in general practice. Meanwhile, the RHIVA2 team evaluated, using a cluster RCT design, whether offering testing in this way would lead to a greater and earlier detection of HIV. While Part 1 described Story 1: ‘the logic of normalisation’ through analysis of the policy context and an exploration of population screening approaches for HIV, Part 2 begins to draw out Story 2: ‘the logic of the pragmatic trial’. Using the Greenhalgh et al. model of the diffusion of innovations for health care organisations, I explore variation in the uptake of rapid testing amongst the intervention practices. Process evaluation methodology is used to identify four case studies demonstrating differential abilities to implement testing.

## Chapter 8: EVALUATING COMPLEXITY: INTRODUCTION TO PART 2

I begin with an exploration of methods and how the research community has broadly aimed to measure and evaluate health interventions, with attention to the important issue of ‘context’. I will then introduce the findings in Chapter 9.

### 8.1 Methodological considerations: The RCT and Its ‘Origin Stories’<sup>9</sup>

RCTs are widely considered the key evaluative design for evidence-based medicine (Goldenberg, 2006). Presently, such trials are known as the ‘gold standard’ and the backbone for producing clinical evidence. Evidence in this case can be considered as ‘information that gives a reason for believing something to be true’ and this supposes an audience for whom this will make a difference (Kelly, 2008). RCTs comprise a number of key components including intervention and control arms, randomisation and blinding (Friedman et al., 2010). Research subjects are randomly allocated to either the experimental arm or the control arm of the study. Commonly, the experimental group receives the health intervention while the control arm continues with care as usual or receives a placebo (Friedman et al., 2010). Randomisation includes assigning subjects to either arm of the study in a random way. This is meant to reduce bias or the potential for confounding variables by ensuring that there is likeness between the 2 arms, save for the intervention being delivered (Singal et al., 2013).

The sample size calculation, which indicates the number of participants required to achieve statistical validity, forms an essential aspect of randomisation, as if the group is too small, the beneficial effect of randomising will not be achieved, invalidating the findings (Friedman et al., 2010). Allocation to arms should be conducted with the help of a technology that removes human bias, such as a random numbers machine (Friedman et al., 2010). Trials can be conducted with variable levels of blinding. Double blinding is considered the strongest design, where both the researchers and the participants are unaware of which research subjects are allocated where (Friedman et al., 2010). Depending on the trial design or the

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<sup>9</sup> I first heard the term ‘origin stories’ used to discuss the history of RCTs during a talk by Ann Kelly entitled: *Ebola Clinical Trials: Accelerated Experiments, Repurposed Evidence* at the Brocher Foundation, February 16, 2015 in Geneva, Switzerland.

intervention, blinding may be more or less possible, in some cases, such as in some pragmatic trials of complex interventions, blinding is not feasible (Foster and Little, 2012).

At the end of the trial, the two groups are compared and, all other factors holding even, the effect of the intervention can be determined. This is considered the beauty and strength of this evaluative technique, a relationship can be determined between the intervention and the outcome and this is claimed to be causal and deterministic of the efficacy of particular interventions (Godwin et al., 2003). These aspects are the tenets of the RCT and are valued for their understood role in reducing bias, controlling for confounders and producing objectivity, causality and rigour. It follows that data produced by this method are interpreted as evidence and subsequently contribute to decision-making in medicine.

Within biomedicine, RCTs have been widely considered the best method of determining the *efficacy* of an intervention. The aim is to control the conditions to maximise the likelihood of an intervention effect (Singal et al., 2013). If, under such conditions, there is a statistically significant effect demonstrated by the intervention, it can be considered to have high internal validity, which is the confidence that the intervention did cause the effect and the subsequent causal implications are valid (Rothwell, 2005). Explanatory trials or efficacy studies are considered a fundamental first step in determining the value of an intervention, determining the efficacy indicates that under controlled conditions the intervention is or isn't effective, allowing for the determination of added values or harms of an intervention (Treweek and Zwanrenstein, 2009).

Recognising methodologies as being historically and culturally situated requires some reference to their origins. A number of scholars exploring the RCT method describe the device in historical context to better understand its current value and historical articulations (Löwy, 2000; Kelly, 2008; Meldrum, 2000). For centuries, the curious have been exploring comparative and controlled methods, developing some of the early foundations of experimentality now integrated into the RCT design (Meldrum, 2000). Marcia Meldrum has done significant work tracing the origins of the RCT and describes these early experiments as doing more to elucidate the value of the comparative method than explore what we might

now term ‘treatment options’ (2000). Meldrum describes how Johannes Fibiger used the earliest well-documented RCT design in 1898 on patients with diphtheria (2000). This was followed in 1930 by a study using a similar method to look at digitalis for pneumonia (Meldrum, 2000). The RCT design increased in value with the burgeoning of drug development and pharmaceutical companies in the early 20<sup>th</sup> century. Doctors and patients felt they had very little means to evaluate the ever-growing number of drug options appearing on the market (Löwy, 2000). Despite the existence of studies using principles of the RCT design, such as the use of controls, large questions about generalisability and replication remained. As a result, clinicians and researchers began to develop methods for the production of what could be considered more robust evidence.

The RCT had some major champions, including Austin Bradford Hill and Archie Cochrane (Kelly, 2008). Bradford Hill wrote a series of papers, published in the *Lancet* in 1937, which mark a period of greater consideration of investigator bias and controlled methods (Meldrum, 2000). Meldrum describes the importance of this move in the quote below:

‘by removing decisions about patient selection and allocation from the physician and forcing the use of standardized, non-qualitative criteria to assess outcome, the RCT model eliminated opportunities for deviation based on physician judgment of bias while providing a powerful basis for conformity’ (Meldrum, 2000: p.753)

Around the same time others developed the principle of blinding and soon came the first attempts at methodological guidance from Feldman, Hinshaw and Mann who published a set of trial design principles that aimed to bring together the emerging thinking in a way that standardised design techniques (1945). The first officially documented randomised controlled clinical trial is often considered the MRC’s 1947 study of the treatment of tuberculosis with streptomycin, which used randomisation, blinding, and intervention and control arms (Meldrum, 2000). For this project Bradford Hill developed a system of random number assignment, despite having stated concerns about the ethics of randomisation (Meldrum, 2000). Bradford Hill is also important in producing a scenario where the unintended effects of trials are clearly evident, his support and enrolment of patients in trials served as a method of enabling access for members of the public to treatments, which were otherwise inaccessible to the patients in need (Stavrou et al., 2014; Kelly, 2008; Meldrum, 2000). This period saw a coalescence of prior work and findings into what was hoped to be a more cohesive, standardised, robust and evidence based method of research design. MRC



designed trials were then successfully replicated in the United States, reinforcing the value of the approach. Ilana Löwy, in her discussion of trials as a ‘soft’ biomedical technology also highlights how the RCT increased the role of the statistician and forced the entry of other ‘experts’ into the biomedical realm, resulting in shifts in the enactments of expertise and decisional power (2000).

Archie Cochrane, himself a student of Austin Bradford Hill and whose legacy as the namesake of the Cochrane reviews and collaborations remains, was also an important figure (Stavrou et al., 2014). He saw the RCT as the key to a rational health service (Kelly, 2008). Cochrane is considered a key paternal figure in the development of evidence-based medicine. Concerned by bias and inconsistency in medicine, he believed the systematic gathering and evaluation of robust evidence was much needed in the British medical service (Stavrou et al., 2014). Cochrane emphasized the importance of experimental methods and systematic reviews, feeling that medical interventions should always be evidence based and that such evidence should be produced in the form of trials (Shah and Chung, 2009; Stavrou et al., 2014). These views culminated in his 1971 monograph: *‘Effectiveness and Efficiency: Random Reflections on Health Services’* which garnered much attention and support (Cochrane, 1971; Shah and Chung, 2009). Cochrane stressed the importance of cost effectiveness and the appropriate and prudent selection of interventions (Shah and Chung, 2009). His insistence on the value of systematically gathering and organising evidence was the impetus behind the Cochrane Collaborations and Reviews (Stavrou et al., 2014).

Much has moved on from the time of Austin Bradford Hill and Archie Cochrane. While RCTs still reign in the hierarchy of evidence, a proliferation of critiques has spawned important adaptations to the traditional trial and a re-thinking of the suitability and application of RCTs to diverse phenomena.

While the benefits of the RCT are widely acknowledged, for some time a growing body of academic work has highlighted the problems inherent to the design (Goldenberg, 2006; Oakley, 1990; Cartwright and Munro, 2010). The majority of critiques of the explanatory trial have fallen around its external validity: the generalisability of the findings to other

groups and situations (Rothwell, 2005). While efficacy is useful it does not take into account the social, cultural and practical interactions that will determine if an intervention can be applied to a representative population of patients (Blackwood, 2010). Some feel RCTs keep medicine focused on disease and not patients and that they fail to incorporate context and the important ‘evaluations grounded in the individualized and embodied skills of the practitioner’ (Löwy, 2000: p.50) as well as the experiential life worlds of patients. The movement of methods from the lab and its crafted environment to an active clinic has a troubled transferable capability (Löwy, 2000). There is a diversity of approaches presented in these critiques. Some feel the solution lies in tinkering with the design of trials to match more complex environments but that a greater challenge to the overarching claims of evidence produced by trials is not required. Others feel that the objectivity and outcomes claimed by the RCT are overstated and represent a portion of reality, that they are crafted within a particular approach to science and thought that could do with epistemological and ontological shift or destabilisation (Cohn et al., 2013; Rosengarten and Savaransky, 2015).

A number of concerns regarding trials also centre on practice. Along with the rise of the trial has been the growth of a number of safeguarding and governance requirements to ensure the ethical use of the method. It is understood that the promise of trials can only be achieved when they adhere to best practice, which is outlined in various stipulations and frameworks (Freedman, 1987). The ever-changing number of articulations of said best practice in the conduct of trials may be summarised through their potential ethical concerns. These are outlined briefly below by trial phase.

In the design stage, important questions concern the general necessity of a trial and the relevance of the research question. This may also bring in more practical considerations around costs and the temporal relevance of the work (Friedman et al., 2010). Here the concept of equipoise - ‘a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial’ - is important (Freedman, 1987:142). Ethically, trials should be discontinued and both arms offered treatment should there an obvious beneficial effect (Freedman, 1987). Additional concerns may arise around the randomisation procedures, the appropriateness of a control group and the acquisition of informed consent (Friedman, 2010). In the enactment of the trial design, issues may arise in

the recruitment, the data collection and the way power is practiced. Trials conducted in resource-poor settings have evidenced some of these concerns through examples of exploitation, coercion to participate and the unethical use of placebos (Miller and Brody, 2002). Additional problems may arise in the reporting phase with publication bias and the lack of reporting on ‘negative trials’ (where findings are not determined statistically significant, signaling a lack of effect), the suppression of trial findings or delays in reporting (Goodchild van Hilten, 2015; Turner et al., 2012). Conflict of interest is woven through the trial process as an overarching concern (Lo et al., 2000).

In summary, conventional RCTs act in various ways. They demarcate a standard, work as an evaluative tool, and are a symbol of contemporary valuations of evidence and science (Löwy, 2000; Kelly, 2008). Moreover, the methods used help create the ‘reality’ produced and measured and a trial in and of itself may be considered an intervention, regardless of what the actual intervention seeking measurement may be (Law, 2004). In some cases, trials may be a mediating device between science, corporations, the government and the public. In others, they may be means for patients to access treatment (Kelly, 2008). In the face of significant dispute and contestation over aspects of the RCT, other designs have emerged, sometimes in an attempt to compensate for the evidence that cannot be produced by this design, in other cases to tinker in ways that allow the beneficial principles of the RCT to remain intact while achieving other stated objectives. The RHIVA2 trial was developed within these approaches. As a pragmatic trial it is meant to be a better directive for evidence related to contemporary health care practice.

## **8.2 Tinkering with trials: The rise of adjunct designs and the pragmatic RCT**

Critiques emerging from the use and status of efficacy trials and the need to evaluate treatments and interventions in practice gave rise to the ‘pragmatic’ clinical trial (Trewick and Zwarenstein, 2009). These trials aim to measure the applicability of an intervention in the ‘real world’ and everyday setting of routine medical practice (Kelly, 2008). Such trials aim to produce results more generalisable and instructive for broad clinical practice with greater utility for policy makers, health professionals and patients (Foster and Little, 20012) (Trewick and Zwarenstein, 2009). The term was first written about in 1967 by Shwartz and

Lellouch, who felt that ‘there is ambiguity about which two radically different kinds of problems they [trials] are designed to address’, referring to the difference between efficacy and effectiveness (Foster and Little, 2012). Eldridge and others discuss a resurgence of interest in the pragmatic trial with an expanding conversation about the best practice, regulatory processes and overall design of such studies (Eldridge, 2010; Sugarman, 2014; Blackwood, 2010; Rothwell, 2005; Kelly, 2008; Singal et al., 2013). This corresponds with a maturing conversation on complex interventions, critiques of evidence based medicine and the appropriate methodologies for acknowledging and measuring complexity and context (Greenhalgh, 2014; Hawe et al., 2004; Mowles, 2014).

Pragmatic trials differ from efficacy trials in various ways in trying to achieve the complementary objective of effectiveness. Pragmatic trials usually include a high external validity, large sample size, an emphasis on diverse settings, a heterogeneous and representative research sample and variations on understandings of bias, such as blinding (Treweek and Zwarenstein, 2009). In a pragmatic trial, procedures should reflect everyday clinical practice, changing as little as possible about the setting in which the interventions and treatments are delivered (Macpherson, 2004; Selby, 2012; Roland, 1998; Treweek and Zwarenstein, 2009; Patsopoulos, 2011). Along with acknowledging the importance of context, and the challenges to the evidence based medicine paradigm, has been a greater proliferation of guidance, tools and reflections on pragmatic trials, making the pragmatic trial a recognised member of the contemporary methodological class (Zwarenstein et al., 2008). The extension of the CONSORT statement to include reporting on pragmatic designs in 2008 is indicative of this (Zwarenstein et al., 2008). Pragmatic trials may also require cluster designs and a more intensive reporting on the specificities of the intervention (Eldridge, 2010). There is increasing acknowledgement that many trials exist on an explanatory – pragmatic spectrum, often containing a mix of elements (Foster and Little, 2012; Eldridge, 2010; Thorpe et al., 2009). This is demonstrated in the PRECIS tool, established to determine the extent to which a trial is pragmatic by thinking through a set of questions, then evaluating against a scale and applying the results to a final PRECIS ‘wheel’, which visualises the extent of a trial’s pragmatic features (Thorpe et al., 2009; Tosh et al., 2011).

As pragmatic trials are meant to be rolled out in ‘everyday’ settings, they often call upon implementers who are not professional researchers, including a wide range of health professionals. This has led to the acknowledgement of the importance of behavioural and relational dynamics in the conduct of trials as well as cognisance of the ‘therapeutic relationship’ and its interaction with trial findings (Foster and Little, 2012; Eldridge, 2010; Sugarman and Califf, 2014). In a pragmatic trial, the practical realities of capacity and economics in the research implementation also weigh in. Primary care research recognises pragmatic trials as an important methodology due to the ‘everyday’ setting, access to patients and range of services normally provided in primary care. Some writing has been focused specifically on the pragmatic trial application in primary care (Foster and Little, 2012; Lancaster et al., 2010; Eldridge, 2010).

Despite how many of these interferences demonstrate how ‘the shackles of simple intervention thinking prove hard to throw off’ (Hawe, 2004: p.1583), the experimental method has continued to gain prominence and attempts are being made to measure a plurality of phenomena using a trial design (Marchal et al., 2013). This has resulted in variable success, with frustration among those who feel their interventions have clear merit but find themselves with insignificant findings and methodologies that do not appropriately reflect their interventions (Munro and Bloor, 2008). This may be in spite of other ‘evidence’ affording value to the intervention. This, in part, has given rise to the greater articulation of ‘complex interventions’ and reflection how best to measure them.

At present, complexity and accounting for context in the measurement of interventions is a pertinent subject in biomedicine. Ray Pawson describes the challenge in the quote below:

‘Every attempt to conduct an evaluation is beset with the impossibility of covering every angle; every attempt to conduct a review is faced with the impracticability of chasing down every single issue. So, too, have the evaluation paradigms floundered in the face of complexity: experimentalists struggle to maintain control over every event, variable, whistle and bell; constructivists ply constructions on the co-constructions of an endless supply of stakeholders; formative evaluators excavate to discover there are processes within processes within processes. And so whether evaluation seeks to judge, describe, inspire or explain, there is an ever-present predicament in claiming to have achieved closure in covering all eventualities.’ (Pawson 2013: p.29)

The literature on complex interventions relates to literature on pragmatic trials, with much conceptual overlap. The MRC defines complex interventions as those health interventions containing ‘a number of components which may act both independently and inter-dependently’ and recognise the challenge this may pose in determining the ‘active ingredients’ exerting an effect (Craig et al., 2008 p.7; Shiell et al., 2008). According to the MRC, this complexity is found in a number of areas including the number of interacting parts, the behavioural dimensions of delivering and receiving interventions, the number of players involved in the process, the recognising and measuring of numerous variable outcomes and the extent to which the intervention can be tinkered with while maintaining fidelity (Craig et al., 2008; Pettigrew, 2011). They may also be difficult to describe and replicate, the pathways and mechanisms of action related to the ‘active’ ingredients may be uncertain or unknown (Lewin et al., 2009). In other words, it is not always clear what makes a complex intervention ‘work’ or not and so the impact of the intervention and the generalisability of findings to other settings can be unclear.

The definitions of complexity presented in the MRC guidance, and the general terms of the conversation on complex interventions, have been problematised. Alan Shiell and Penelope Hawe were some of the first to distinguish between complexity and complicated in relation to complex interventions (Shiell et al., 2008). They outline complexity as drawing from complexity science and discuss the term as the property of a system versus an intervention (Shiell et al., 2008). In this sense, a complex system is: ‘adaptive to changes in its local environment, is composed of other complex systems (for example, the human body), and behaves in a non linear fashion (change in outcome is not proportional to change in input)’ (Shiell et al., 2008: p.1291). The difference may not always be easy to tease out but this approach suggests a wider consideration of an ecological approach and the macro and micro interactions inherent to complex systems. Cohn et al. also seek to pull apart the term ‘complex intervention’, again problematising the definition of complexity:

‘addressing complexity requires more than the simple adoption of an ever expanding number of variables or array of statistical tests. Rather, we have suggested that the notion of ecological complexity perhaps best captures the specific dynamics of complexity in the domain of health and illness. Such an approach emphasizes not only how different elements come together to produce a system but also how such

elements become meaningful and change as they travel through and interact in particular contexts.’ (Cohn et al., 2013: p.42)

The acknowledgement of complexity as related to context, relations, interaction and situated dynamics has been raised by a number of scholars who call for a re-tooling of methods and concepts to better suit the ‘real world’ (Hawe et al., 2004; Shiell et al., 2008; Cohn et al., 2013; Greenhalgh et al., 2014); a world rife with complexity and seemingly limited in its methodological options.

Some have used lenses such as realist evaluation in approaching complexity (Pawson and Tilley, 2006). The approach was suggested as a potential approach for the RCT (Bonnell et al., 2012), but was refuted, including by Pawson himself (Marchal et al., 2013), demonstrating the challenge in aligning epistemologies, research strategies, methods, data and reporting in the time of experimental effectiveness studies and complex interventions.

‘Fidelity’ is considered a key aspect of the RCT design and the measurement of interventions. Simply put, fidelity can be considered whether the intervention was ‘delivered as planned’ which would allow for the ascertainment of the interventions effect on the outcome and lend support to the research conclusions (Horner et al., 2006: p.80). A call for reconsideration of the concept of fidelity in the measurement of complex interventions and pragmatic trials has been discussed (Hawe et al., 2004; Moore et al., 2014). When attempting to replicate trial designs and demonstrate wide-scale applicability, it is suggested that the traditional concept of fidelity could be altered, losing some of its literal precision while maintaining the overarching concepts (Hawe et al., 2004). Acknowledging the importance of situational factors (time, place, people, culture etc.) may mean that an intervention can be delivered in different settings in a way that adapts aspects of the intervention, and admits their relevance to the evaluation, while retaining conceptual congruency so that the intervention is faithful to trial features. Hawe and Shiell suggest it may be prudent to define fidelity functionally rather than compositionally (Hawe et al., 2004). This is considered in the most recent guidance on process evaluation in complex intervention evaluations, produced by the MRC (Moore et al., 2014).

The contributions of social science have been widely recognised in the field of medicine and a number of researchers have been keen to determine the ways qualitative and quantitative data could be more meaningfully coupled (Lewin et al., 2009; O’Cathain et al., 2008; Hesse-Biber, 2015). Despite this acknowledgement and advances in ‘mixed’ methodologies, doubt remains regarding the actual proliferation and successful combining of the approaches (O’Cathain, et al., 2008; Lewin et al., 2009). A systematic review by Lewin et al. in 2009 demonstrated that research teams have involved qualitative methodologies alongside trial designs but true integration, in the form of inclusion at the design and analysis phases, was uncommon. More often, qualitative methodologies were ‘tacked on’ either before or after and quite often reported separately (Lewin et al., 2009; O’Cathain et al., 2008). Despite this, enthusiasm remains and qualitative methods have even been included in the Cochrane reviews (Gülmezoglu et al., 2013), a hallmark of experimental evidence and evidence based medicine.

Some critiques of mixed methods research relate to the longstanding incommensurability thesis, suggesting that methods developed in particular paradigms and with radically different philosophical underpinnings cannot be meaningfully mixed (Lincoln and Denzin, 2011; Hesse-Biber, 2015). In her paper ‘*Mixed Methods Research: The Thingness Problem*’, Hesse-Biber suggests getting past the ‘thingness problem’ in mixed methods research, a problem she suggests is reflected in the formalisation of mixed methods approaches, the ‘unexamined belief in the ‘synergy’ of mixed methods and the growing approach of ‘whatever works’ as the philosophical stance to the mixing of modes of inquiry (2015: p.776). Hesse-Biber’s analysis serves as a useful summary of various critiques of mixed methods and she emphasises reflexivity, considering power and control, the articulation of the research question and generally a more thoughtful engagement with cross disciplinary work as a way forward (2015). Greater reflection of the impacts of working with different epistemological and ontological assumptions will be considered throughout the thesis.

Alongside conversations on the evaluation of complex interventions has been a growing interest in process evaluation as a research method. This approach was described in Chapter 4. This evaluative strategy can be used alongside an RCT to better illuminate the relational, experiential, processual and other ‘gaps’ not covered by traditional experimental designs



(Moore et al., 2014). Essentially, process evaluation alongside an RCT allows each method to ‘retain their paradigmatic natures but are intermeshed with each other to deepen understanding of the phenomenon under study.’ (Munro and Bloor, 2010) The idea is that the process evaluation can unpack the ‘black box’ of what ‘truly’ happens throughout the trial process, and produce explanatory data to better guide decisions and future implementation in other or wider scale settings. Process evaluation explores implementation, setting, delivery, uptake and other possible aspects of interventions and can be useful in interpreting and explaining outcomes (Moore et al., 2013). They may also determine important differences between delivery sites in multi-centre or cluster trials, or help determine which aspects of interventions are linked to which effects (Oakley et al., 2013). Importantly, process evaluations can help determine whether the intervention itself is ineffective or if there has been a problem with the study conduct or implementation process (Oakley et al., 2006).

‘Typically aspects evaluated would include fidelity to the implementation plan, intervention dose delivered and received, the level of reach or participation, the recruitment process and the ‘context’ (Saunders et al., 2005).

For example, a trial on peer-delivered sex education in scholastic settings with an integrated process evaluation, by Oakley et al., used surveys, focus groups, interviews, observations and field notes and a number of innovative statistical techniques, developed in an attempt to meaningfully combine the various forms of empirical data, to develop an in-depth understanding of the intervention. The results provided nuanced findings that allowed for the teasing out of the value of consistency of implementation and what might be the key interactions and circumstances in which the intervention is most likely to be effective (Oakley et al., 2006). Process evaluation shows explanatory promise for understanding negative trial findings as well and may allow for the finer tuning of interventions to environments (Munro and Bloor, 2010).

While some see the combining of process evaluation alongside trials as the way to maximise the benefits of experimental designs but account for complexity, pragmatism and context, others still see the approaches as incompatible (Munro and Bloor, 2010). Alison Munro and Michael Bloor clearly highlight some of these tensions in their article ‘*Process Evaluation: the new miracle ingredient in public health research?*’, concluding that process evaluation is

not a miracle at all (2010). Challenging some of the touted best practice of process evaluation such as conducting the preset analysis plan prior to the outcome analysis so as not to influence the findings, they stress how without this ‘20/20 hindsight’ at the design stage the process evaluation is not able to account for emergent or unexpected findings using this evaluative sequencing (Munro and Bloor, 2010). Additionally, they discuss how qualitative research uses inductive thinking and how this sits in contrast to ‘pronouncing’ generalisability and external validity; how making generalisations from contextually situated instances may be problematic, an epistemological tension discussed elsewhere in the thesis (Munro and Bloor, 2010). They conclude that it is ‘a mistake to think of qualitative and quantitative findings as commensurate in some straight-forward fashion’ (Munro and Bloor, 2010). Despite this, other researchers have found the inclusion of process evaluations alongside trials to be fruitful in gaining explanatory insights into research outcomes (Oakley et al., 2006).

### ***Situating Efficacy***

Considering the philosophical underpinnings of the RCT and undertaking critical work on the ontological assumptions inherent to research designs is another approach to accounting for the challenges of evaluative strategies. In 2015, a conference entitled *Situated Efficacy: Biomedicine, Interdisciplinarity and the Politics of Intervention* was held at the Brocher Foundation. Academics writing in the fields of sociology, anthropology, design, translational research, international health policy and public health sciences were invited to submit texts discussing the ways in which our current experimental evaluative models and specifically the concept of efficacy, as produced by trials, isn’t ‘working’ (Rosengarten and Savaransky, 2015). As a result, a set of unpublished papers was produced that speak around the concept of ‘situated efficacy’. This work is introduced here as it evidences new forms of interdisciplinary thinking about research designs and enactments. This is an example of a radical conceptual shift to the thinking underpinning current explanatory and pragmatic trials and a call for an interdisciplinary approach to tackling contemporary methodological queries, upfront in its philosophical stance.

Marsha Rosengarten and Martin Savaransky wrote the concept papers to orient the event. Essentially this work tries to trouble the concepts of efficacy and effectiveness. Roughly, using concepts from Alfred North Whitehead and other pragmatist thinkers such as Dewey and James, the conference leads asked how the current conceptualisations and enactments of trials limit what is knowable. They challenged the static approach to reality inherent in the trial design and wondered how weaving speculation into our methods might allow for the emergence of different and more helpful data, knowledge and representations (2015). They problematise the boundaries created by the current mobilisations of ‘efficacy’ and ask what is left out and if these modes of inquiry in fact produce the evidence they claim and whether such evidence is in fact helpful. They ask what happens during the process of translating an efficacious treatment into an effectiveness trial and what is lost, overridden, closed down and unconsidered in such a translation (2015).

‘the distinction between ‘efficacy’ and ‘effectiveness’ upon which RCTs rest, makes available a specific centre-periphery mode of multidisciplinary: biomedical researchers deal with the central question of ‘efficacy,’ while social researchers, policy makers and implementers (in public and non-government organisations) engage with contextual issues and practices of remediation rendered peripheral to the intrinsic success or failure of an intervention itself.’ (Rosengarten, 2015: p.1)

If health is a process of becoming, or a state of continuous positive adaptation, and reality is processual and emergent, then how do our current evaluative tools account for this, or not? ‘Situated efficacy’ therefore calls for a research design that acknowledges the processual nature of reality, bodies and interactions, that accepts speculation and uncertainty as necessary, essential and potentially helpful in research despite the challenges this may present to current valuations and concepts of ‘generalisability’ and applicability’ (Rosengarten and Savaransky, 2015). This work will be further discussed in Part 3.

At times it is unclear what the suggested direction of travel might be within the various critiques of the aforementioned methods and their suggested remedies. It appears that a number of researchers are happy to ‘tinker’ with the current set of evaluative designs, hoping to incrementally reduce the relevance of such criticisms. This may include beginning to use adaptive trial designs, for example, or further refining the design elements of a pragmatic trial (Hirschhorn et al., 2015). Others appear to suggest a re-tuning of the hierarchy of evidence, with an emphasis on better matching research to its questions and situations along with a greater valuation of methodologies employed in the realm of social science, as a way

forward. The rise of mixed methodologies is an example of this. Others still would describe the above as a never-ending quest to ‘capture’ context, a band-aid set of alterations to deeper epistemological problems and a resistance to the radical rethinking required. Such scholars would prefer a re-conceptualisation of our tools, environments and interactions that allows for ruptures in widely held views of reality, science and evidence (Savaransky and Rosengarten, 2015; Cohn et al., 2013; Mol, 2002). What can be concluded, however, is that a greater and more modest claim to what experimental research tools can and do produce, and what can be considered evidence, may be required.

What does this mean for the overall doctoral project? The pragmatic, cluster trial approach used in the RHIVA2 trial was born of critiques of the traditional RCT. The design is meant to include more ‘reality’ and to guide clinical practice with its findings. The RHIVA2 intervention is seen as effective, however, the trial presents a partial view, much else was taking place. The intervention of rapid HIV testing has complex features but still sits fairly low on the scale of complex interventions. The rapid test is short and requires a single occasion of consent and participation for most patients. Despite this, the setting, the social reality of HIV infection and the behaviour change required by health professionals add to the complexity. The conducting of a retrospective process evaluation has been useful in gaining insights into the implementation process. In the findings to be presented below, some of the complexity of the RHIVA2 trial becomes clear. The model used to elicit some of this complexity is the Greenhalgh et al. model of the diffusion of innovations in healthcare settings (Greenhalgh et al., 2004).

## **Chapter 9: EXPLAINING THE VARIATION IN RAPID HIV TESTING AMONG RHIVA2 INTERVENTION PRACTICES USING DIFFUSION OF INNOVATIONS THEORY**

‘To a greater or less extent (and differently in different contexts), individuals seek innovations out, experiment with them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them, challenge them, worry about them, complain about them, develop know how about them, modify them to fit particular tasks, and attempt to improve or redesign them – often (and most successfully) through dialogue with other users. Furthermore, except in a few circumstances, organisations should not be thought of as rational decision-making machines that move sequentially through an ordered process of awareness-evaluation-adoption-implementation. Rather, the adoption process should be recognised as complex, iterative, organic and untidy.’ (Greenhalgh et al., 2008: p.113)

The work of this chapter has also been published in a paper: *Explaining variation in an HIV testing trial: A new model based on diffusion of innovations theory* by myself and colleagues (McMullen et al., 2015) (attached as Appendix 1). Both my supervisors and another investigator from RHIVA2 were co-authors; a contributorship statement is included in the paper.

### **9.1 Introduction**

As discussed in the introduction and methods chapter, process evaluation is a methodology with increasing application to RCTs. The qualitative and process focussed aspects of the method are meant to illuminate the implementation process, test theory and explore model-reality gaps (Moore et al., 2015; Lewin et al., 2009). While trials are meant to indicate if an intervention ‘worked’, a process evaluation might aim to elucidate ‘how’ the results took hold.

In this chapter, I use process evaluation methodology along with the diffusion of innovations in health care organisations model by Greenhalgh et al. to explore the variation of uptake of rapid HIV testing in RHIVA2 intervention practices (Greenhalgh et al., 2004). Wide variation was seen in the uptake of rapid testing amongst the 20 RHIVA2 intervention

practices, with some practices offering tests in the single digits and others offering over 1000 tests (Leber et al., 2015). The aim of this section is to better understand what went on in the process of the trial and explore factors which facilitated and impeded the uptake of testing. The research explored here was my entry point into the PhD project and was the site where the two stories structuring the thesis became apparent. In RHIVA2 the ‘logic of normalisation’ was being implemented through the intervention of HIV screening as part of the new patient health check (Story 1) and this was being evaluated through a pragmatic trial design (Story 2). On site, in 20 general practice organisations this chapter begins to reveal some of the trial ‘surplus’ and collect information that was not considered as ‘data’ in the trial logic.

## **9.2 Theoretical frame**

The emerging field of implementation science in healthcare emphasises the exploration and understanding of processes in which interventions are implemented, adopted and enacted in their contexts of use and promotes the uptake of research findings on such processes into routine practice (Damschroder et al., 2009; Nilson, 2015). Research related to implementation aims to:

‘recognize the need to evaluate not only summative endpoint health outcomes, but also to perform formative evaluations to assess the extent to which implementation is effective in a specific context to optimize intervention benefits, prolong sustainability of the intervention in that context, and promote dissemination of findings into other contexts’ (Damschoder et al., 2009: p.1)

Various theories, models and frameworks have been developed to explore the implementation process and range from those considering specific factors affecting implementation to those which aim to consider the broader process from multiple dimensions and others which do not aim to reveal processual aspects but evaluate interventions being implemented (Nilsen 2015). Nilson, in his wide-ranging review, articulates five approaches to implementation research: process models, determinant frameworks, classic theories, implementation theories and evaluation frameworks (2015).

The theoretical approach chosen here is diffusion of innovations theory. According to Nilson, this is a *classic* approach to exploring implementation and considered ‘the single most influential theory in the broader field of knowledge utilisation of which implementation is a part’ (Nilson 2015: p.7). Everett Rogers developed this approach to evaluating innovation adoption in the 1950s to explain the adoption and spread of innovations by individuals in a social network (Rogers, 2003). Greenhalgh et al. extended the theory in 2004 specifically to the healthcare setting and to address the assimilation and implementation of service-level innovations in health care organisations (Greenhalgh et al., 2004). In 2010, Robert et al. published an update to that systematic review, using a similar search strategy that aimed to identify more recent publications (Robert et al., 2010). The review confirmed the findings of the 2004 study and in particular validated the model produced by these authors in 2004; additional empirical studies were found in relation to the routinisation and sustainability of innovations (on which there had been little data in the original review).

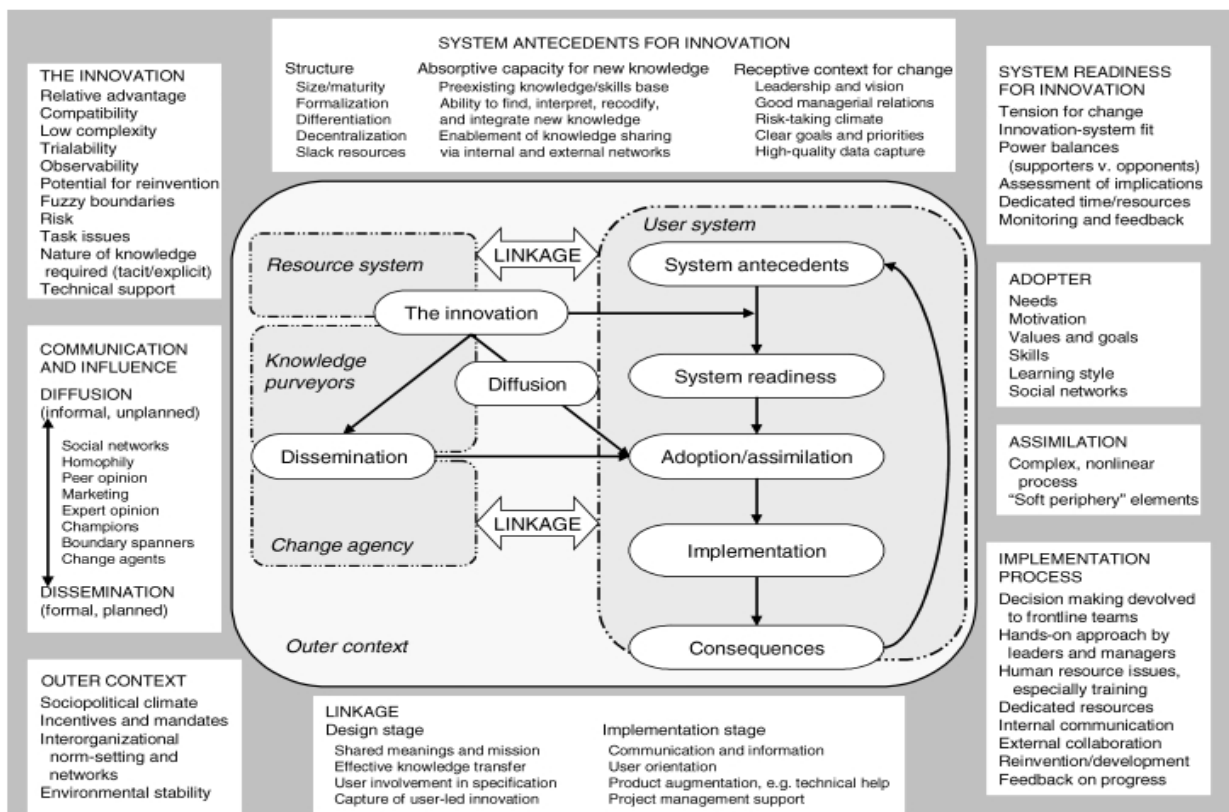
Greenhalgh et al. define an innovation as ‘a novel set of behaviours, routines, and ways of working that are directed at improving health outcomes, administrative efficiency, cost effectiveness, or users’ experience and that are implemented by planned and coordinated actions’ (Greenhalgh et al., 2004: p.582). The definition offered by Greenhalgh et al. aligns with the MRC definition of a complex intervention (see the introduction to Part 2) where an intervention comprises multiple elements, all of which seem essential but whose ‘active ingredient’ may be difficult to specify as they typically operate at multiple levels (individual, team, organisation) (Campbell et al., 2000; Craig et al., 2008; Guise et al., 2014).

In RHIVA2, as discussed in the Background chapter, the innovation was not solely the rapid HIV test but also the tests offer as a part of a screening program for new registrants in primary care. In the Greenhalgh et al. model, which synthesizes work of previous authors, innovations are conceptualised as having a ‘hard core’, the elements that constitute ‘fidelity’, and are less changeable, and the ‘soft periphery’, which can and must adapt to accommodate it, concepts developed from the work of Denis et al. (Denis et al., 2002). Here the ‘hard core’ could be considered the rapid HIV test itself, and the ‘soft periphery’ aspects, the tests location in the primary care new registrant check. The Greenhalgh et al. model was chosen

because of its emphasis on the innovation itself, which in the case of population screening for HIV, and the novel entry of rapid testing into this setting, was considered a key aspect in need of in-depth exploration (May, 2009; Murray et al., 2010).

Greenhalgh et al.'s wide-ranging systematic review of the diffusion, spread and sustainability of innovations in the organisation and delivery of health services identified six interacting components: (1) the innovation itself; (2) the intended adopters; (3) communication and influence; (4) the inner organisational or system context, comprising general antecedents for innovation-specific readiness for a particular innovation; (5) the outer (inter-organisational and environmental) context; and (6) the implementation process. The model emphasises the importance of linkage between different components of and feedback regarding the consequences of innovation to other parts of the system. The Greenhalgh et al. model is summarised in the diagram below:

**Figure 5.** Greenhalgh et al.'s diffusion of innovation model (Greenhalgh et al. 2004: p.595)





Applying this model to RHIVA2 was not straightforward. This may have been in part due to the model’s retrospective application but also because of the trial’s pragmatic nature, where we were aiming to measure the ‘real world’, a task which will be more deeply considered in Part 3 of the thesis. Some aspects of the model appeared as immediately less relevant due to the context of the trial, where attributes such as communication and influence were included as part of the trial’s training programme, which was standardised across intervention practices. Nevertheless, the pragmatic design of the trial meant that many real-world influences were built into the study design. For example, participating practices were open to communication from other practices locally as well as from other, ‘outer context’ influences, such as the economic recession, new immigration and changes in national and local HIV policies, as discussed in Part 1 of the thesis.

The following table summarises the key components of the model.

**Table 7.** Components of the diffusion of innovations model represented by McMullen et al. 2015 from work by Greenhalgh et al. (McMullen et al., 2015: p.5; Greenhalgh et al., 2004).

COMPONENT	DEFINITION	
<b>Attributes of the innovation</b>	How the potential adopter views the pros and cons of the innovation	
	<b>Relative advantage</b>	A clear, unambiguous advantage in terms of either effectiveness or cost effectiveness.
	<b>Compatibility</b>	Compatible with the values, norms and perceived needs or intended adopters.
	<b>Low complexity</b>	Composed of simple, easy to implement steps. Able to be broken down and learned on an incremental basis.
	<b>Trialability</b>	Can be experimented with.
	<b>Observability</b>	Benefits are (or quickly become) visible to intended adopters.
	<b>Potential for reinvention</b>	Possibility to adapt, refine or otherwise modify the innovation to suit adopter needs.
	<b>Fuzzy boundaries</b>	If innovations have ‘hard cores’ (irreducible elements of the innovation) and ‘soft peripheries’ (structures and systems required for full implementation) adaptation of the soft periphery can facilitate adoption.
	<b>Risk</b>	Risks of the innovation (as perceived by the intended adopter) are outweighed by its perceived benefits.
	<b>Task issues</b>	Extent to which the innovation is relevant, feasible, workable and easy to use for the adopter.
	<b>Nature of knowledge</b>	Knowledge required to enact the innovation can be transferred – either by codification (explicit knowledge) or more informally e.g. shadowing (tacit knowledge).
<b>Technical support</b>	If the innovation is technical, helpdesk support is available, especially in the early stages of implementation	
<b>System antecedents for innovation (Including</b>	Extent to which the organisation is ready for innovations in general.	

<b>structure/ absorptive capacity/receptive context)</b>		
<b>Structure</b>	<i>Size/ Maturity</i>	Practice size is related to innovation adoption with larger practices faring better regarding implementation. A proxy for other features such as slack resources and functional differentiation.
	<i>Formalisation</i>	The extent to which there are rules and protocols regarding organisational activities which are upheld.
	<i>Differentiation</i>	The extent to which roles and activities are divided.
	<i>Decentralisation</i>	Decision making power is appropriately dispersed across organisations.
	<i>Slack Resources</i>	The resources an organisation has beyond what it minimally requires to maintain operations.
<b>Absorptive capacity for new knowledge</b>	A dynamic capability pertaining to knowledge creation and utilisation that enhances an organisation's ability to gain and sustain a competitive advantage.	
	<i>Pre-existing knowledge / skill set</i>	Existing knowledge and skills within the organisation. Particularly facilitatory if somehow related to the innovation.
	<i>Ability to find, interpret, re-codify and integrate new knowledge</i>	The ability to take on, understand, integrate into existing systems and put it to productive use new information.
	<i>Enablement of knowledge sharing via internal and external networks</i>	Individuals are able to share knowledge regarding the innovation internally and externally through established networks.
<b>Receptive context for change</b>	A combination of factors from both the inner and the outer context that together determine an organisation's ability to respond effectively and purposefully to change.	
	<i>Leadership and vision</i>	Top management support, advocacy of the implementation process and continued commitment enhance the success of implementation and routinisation.
	<i>Good managerial relations</i>	Staff have positive relationships with managers.
	<i>Risk-taking climate</i>	A supportive working culture where practice staff feel able to experiment with new innovations without fear of reprimand.
	<i>Clear goals and priorities</i>	Objectives are clear to the organisation and the staff.
	<i>High-quality data capture</i>	Organisational systems are in place to obtain high quality data related to the innovation diffusion.
<b>System Readiness for Innovation</b>	The extent to which the organisation is ready for the specific innovation.	
	<i>Tension for Change</i>	If adopters see the current situation as inadequate or intolerable.
	<i>Innovation System Fit</i>	The innovation fits with existing values, norms, strategies, goals, skill mix, supporting technologies and ways of working in the organisation.
	<i>Power Balances</i>	How power and authority is attributed and operating in the organisation.
	<i>Assessment of implications</i>	The implications of adoption are known and assessed.
	<i>Dedicated time/resources</i>	There is budget and resource available that is adequate and recurrent.
	<i>Monitoring and feedback</i>	Systems and skills are in place to monitor and evaluate the impact of the innovation and feedback to adopters.
<b>Adopter</b>	Those meant to adopt and enact innovations.	

	<i>Needs</i>	What the adopter needs to be able to adopt the innovation.
	<i>Motivation</i>	Whether the adopter is motivated to adopt the innovation.
	<i>Values and goals</i>	Does the innovation gel with the adopter's values and goals.
	<i>Skills</i>	The skills required to adopt the innovation and whether adopters posses these.
	<i>Learning style</i>	The ways that adopters learn are considered and catered to in the innovation training.
	<i>Social networks</i>	The pattern of friendship, advice, communication and support that exists among members of a social system.
<b>Implementation Process</b>		The process by which a new innovation is diffused across an organisation.
	<i>Decision making devolved to front line teams</i>	Do lead users of the innovation have control over aspects of the implementation process?
	<i>Hands-on approach by leaders and managers</i>	Leaders and managers are involved in the implementation process, supporting and assisting problem solving as required.
	<i>Human resource issues, especially training</i>	Have all human resource issues linked to the introduction of the innovation (training, workload, supervision, performance management) been adequately addressed?
	<i>Dedicated resources</i>	Specific resources of time, budget and other relevant resource are dedicated to support implementation.
	<i>Internal communication</i>	Involved bodies communicated effectively with each other regarding the innovation and the implementation process.
	<i>External collaboration</i>	Effective knowledge-sharing links to other organisations who are implementing the same innovation.
	<i>Reinvention/ Development</i>	Was it possible to adapt the innovation or the tasks and processes associated with it to suit local contingencies?
	<i>Feedback on progress</i>	Are there evaluative and feedback mechanisms in place and enacted?

This section of the thesis calls on process evaluation methodology to construct the findings. See Chapter 4 section 4.5 for a broader discussion of the process evaluation method.

### 9.3 Method and Data Sources

Methods were described in Chapter 4. I will briefly outline the data sources.

Data were collected through various methods. Interviews were conducted with 23 RHIVA2 intervention practice staff. Performance data from the RHIVA2 trial as well as practice level data collected throughout the study is also used. Ethnographic field notes were called upon. The interview questionnaires were semi structured to allow for comparison and responsiveness to participants' experiences. The study used purposive sampling. Providers of

practices in the intervention arm of the RHIVA2 trial who had a role in offering rapid HIV testing to new patients were invited to take part in the qualitative study. The sample primarily included nurses and health care assistants who were charged with offering the rapid HIV testing as a part of the new patient health check. Practice managers and general practitioners were also invited if they had a role in rapid testing, either through the management of patients who were diagnosed as positive through rapid testing or through overall coordination of the testing within the practice.

Providers from 16 of the 20 intervention practices participated in interviews. Three non-participating practices had closed and dropped out of the trial at the time of interview request. Others never returned the invitation after repeat attempts. A total of 23 providers were interviewed: eight health care assistants, twelve nurses, one practice manager, one clinical manager and one GP. See Table 8 for a presentation of sample characteristics.

Two of the interviews were conducted in pairs upon request of the participants. In both cases this was with a nurse and healthcare assistant pairing. Interviews lasted between 30 and 60 minutes and took place at the practice during regular practice hours. Written informed consent was obtained from all participants. Participants were provided with a £10 voucher as compensation.

Research participants are described in Table 8.

**Table 8.** *Provider interview participant characteristics*

	<b>Role</b>	<b>Sex</b>	<b>Age Range</b>	<b>Length of time at the practice</b>	<b>Level of employment at the practice</b>	<b>Specific experience working with HIV</b>
1	Nurse	Female	Over 60	>3 yrs	Part time	No
2	HCA	Female	21-30	>3 yrs	Full time	No
3	HCA	Female	41-50	>3 yrs	Full time	No
4	HCA	Female	41-50	>3 yrs	Part time	No
5	Nurse	Female	51-60	>3 yrs	Part time	No
6	Nurse	Female	51-60	>3 yrs	Full time	Yes, in substance misuse centre
7	Nurse	Female	41-50	>3 yrs	Full time	No
8	Nurse	Female	31-40	< 1 yr	Part time	Yes, insurance testing
9	Nurse	Female	51-60	1-3 years	Part time	Yes, care for HIV patient
10	Nurse	Female	41-50	>3 yrs	Part time	No
11	HCA	Female	31-40	>3 yrs	Part time	No
12	Clinical Services Manager	Male	31-40	>3 yrs	Part time	No
13	HCA	Male	21-30	1-3 years	Full time	No
14	GP	Male	Over 60	>3 yrs	Part time	No
15	Nurse	Female	41-50	>3 yrs	Full time	No
16	HCA	Female	21-30	>3 yrs	Part time	No
17	Nurse	Female	51-60	>3 yrs	Part time	No
18	Nurse	Female	51-60	1-3 years	Part time	No
19	Nurse	Female	51-60	1-3 years	Part time	Yes, as Infection and Immunity Nurse
20	HCA	Female	31-40	>3 yrs	Part time	No
21	Practice Manager	Female	51-60	>3 yrs	Full Time	No
22	HCA	Female	41-50	>3 yrs	Part time	No
23	Nurse	Female	41-50	>3yrs	Part time	No

Data analysis occurred in three phases. The first phase involved preliminary familiarisation and coding and asked the question: What were the experiences and perspectives of providers of rapid HIV tests in primary care? The second phase involved the application of a coding frame related to the diffusion of innovations model and asked: What enabled or hindered providers in effectively implementing rapid HIV testing in general practice? The third phase involved the synthesis of data into case studies.

Qualitative transcripts (field notes, interviews and extracts from emails and documents) and matched demographic data on interviewees were uploaded into NVivo software and framework analysis was undertaken (Spencer et al., 2003), first for familiarity and then using codes developed related to the Greenhalgh et al. model of the diffusion of innovations. Box 2 below demonstrates the application of the Greenhalgh et al. model to the topic guide to determine the coding frame.

**Box 2.** Example of coding frame for provider semi structured interviews

QUESTION	Coding Theme – DOI Model	RESPONSE
1. What are your thoughts about providing rapid HIV Testing in Primary Care?	A.2 Compatibility H.1- Tension for Change H.2 – Innovation System Fit	
2. What do you think the impact of testing in primary care is?	H.4- Assessment of Implications H.2 Innovation System Fit G.3 Values and Goals	
3. HIV is often dealt with within specialist services. What do you think about providing a service commonly provided in specialist settings in general practice?	H.4- Assessment of Implications H.2 Innovation System Fit A.2 Compatibility G.3 Values and Goals	
4. How does a new GP surgery need to be equipped to deal with a new HIV diagnosis? What does a surgery need?	H.5 – Dedicated time and resources G.4 Skills	

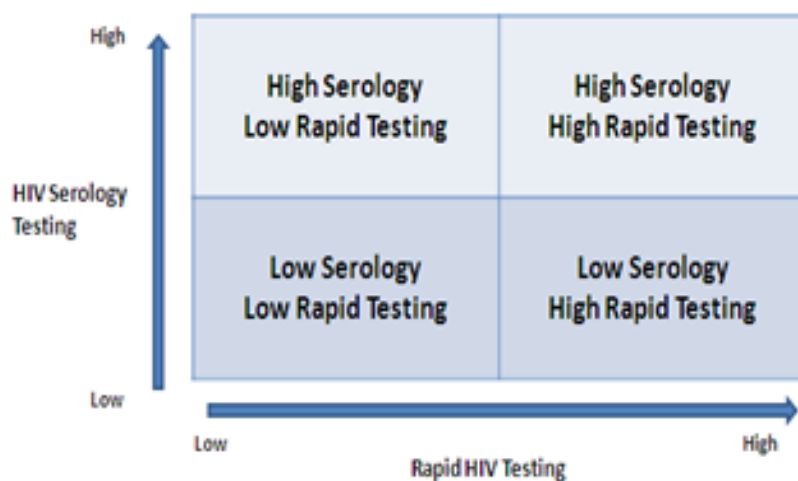
A spreadsheet of practice size, male HIV testing rate prior to the trial, rapid HIV and serological testing and practice HIV diagnoses during the trial period was developed to assist in determining the sampling frame for the cases. One surprising finding was that practices that had had high rates of HIV serological testing before the trial, which was considered a proximal factor for awareness and interest in HIV were not necessarily high performers in

RHIVA2. This sampling frame allowed me to explore the innovation as compared to regular HIV testing practice (serology testing) across RHIVA2 sites and consider implementation related factors. The four chosen practices aligned with the sampling frame as follows:

- Practice A: high serological testing, high rapid testing.
- Practice B: low serological testing, high rapid testing
- Practice C: low serological testing, low rapid testing
- Practice D: high serological testing, low rapid testing

The sample frame is pictured in Figure 6 below.

**Figure 6.** Sampling strategy for case study construction in the provider-level study



This sampling frame allowed for the determination of four cases to be further developed. A ‘thick’ file was developed for each case study and included interview transcripts, ethnographic field notes, trial performance data and practice level data such as information about the ward in which the practice was situated and practice size and structure. To aid in the analysis, a one-page crib sheet on the case studies relationship to attributes from the Greenhalgh et al. model was developed.

A worked up example is displayed in Figure 7 below

Figure 7. Example of case study findings summary used in analysis

<p><b>The Practice: X</b></p> <p><b>Practice Size:</b> XXXX  <b>Location:</b> Ward with 20% lowest Dep Scores in London – XXXX  <b>Number of Professionals:</b> XXXXXXXXX  <b>Maturity:</b> longstanding  <b>Slack Resources:</b> Yes – quiet surgery, XXX NPHC, staff provided lunches, space  <b>Absorptive Capacity:</b> keen to be involved  <b>Receptive Context for Change:</b> seemed open to learning – asked more questions than other practices  <b>Managerial Relations:</b> Seems like a clear division of roles and labour  <b>Risk Taking Climate:</b> Moderate  <b>Clear goals and priorities:</b> Unclear  <b>High Quality Data Capture:</b> XXX system. Nurse accidentally took written consent from each patient. Timely and consistent in QA and she had a very organised office.</p>	<p><b>The Innovation, the Practice, the Adopter:</b></p> <p><b>Relative Advantage:</b> Practice saw the innov as having this, speed / NPHC / needs  <b>Compatibility:</b> Yes, fit with their goals  <b>Observability:</b> Important factor here, early reactive, supported by 3 more  <b>Potential for Reinvention:</b> Yes – Referred by GP XXXX  <b>Fuzzy Boundaries:</b> Referred from GP? Fuzzy boundary of the offer?  <b>Risk:</b> She felt emotional risk in the management of reactivess  <b>Task Issues:</b> Clearly defined roles present  <b>Nature of Knowledge:</b> Appropriate until reactive  <b>Technical Support:</b> Provided by the study team  <b>Tension for change:</b> None indicated - low serology testing practice  <b>Innovation System Fit:</b> Good  <b>Power Balances:</b> Good  <b>Assessment of Implications:</b> Good  <b>Dedicated Time and Resources:</b> Important XXXX  <b>Monitoring and Feedback:</b> We provided this to her and her practice</p>
<p><b>The Adopters:</b></p> <p><b>Characteristics of Provider:</b> Good bedside manner, organised, possibly pedantic, saw the value in testing, concerned by patients, respects the doctors. Wanted to do a good job - F/T – XXXXX  <b>Needs:</b> Regularly asked for clear directives when required. Got in touch if ever needed extra supplies.  <b>Motivation:</b> Discussed doing 'good' for patients and the public  <b>Values and Goals:</b> Talks about things being 'good' – Seems to value doing a good job, being organised and performing well. Was quite upset by challenges XXXX  <b>Experience of Quality Assurance:</b> Mixed. Struggled with XXXX process and regular participation and follow up nonetheless -  <b>Feelings about testing:</b> Positive, fear of reactivess</p>	<p><b>Trial Performance:</b></p> <p><b>Rapid Tests Offered:</b> XXX  <b>Rapid tests performed:</b> XXX  <b>Serology Tests Performed:</b> XXXX  <b>Declined Rapid Tests:</b> XXXX  <b>HIV Positive Patient Detected:</b> XXXX  <b>Comparative Performance:</b> One of the best practices considering practice size/ XXX/provider offering and lower registration level, highest INSTI detection of any practice – best decline rate all other things considered</p>
<p><b>The Implementation Process:</b></p> <p><b>Devolved decision making:</b> She was tasked with testing and left to it  <b>Hands on approach by leaders and managers:</b> Supported with time and GP also referred patients to her  <b>Dedicated Resources:</b> Time was there for testing and space.  <b>Internal Communication:</b> Seemed good between herself and GP over positive cases  <b>Reinvention/Development:</b> GP referred patients to her (outside algorithm) and she did the test away from the patient ( for emotional comfort)  <b>Feedback on Progress:</b> We did a mid study visit and presented her good work to her managers - she was proud  <b>User orientation:</b> n/a <b>Product Augmentation:</b> n/a <b>Project Management Support:</b> By us</p>	<p><b>PRACTICE X:</b></p> <p><b>SAMPLING:</b> Chosen as a case study due to it's excellent innovation adoption and high detection through rapid testing.  <b>SYNOPSIS:</b> A combination of reinvention, adopter qualities, role comfort, dedicated time and resources and encouragement to test due to observability of test benefit.</p> <p><b>DISCUSSION / RECOMMENDATIONS:</b> Provide adequate support and resource, allow for reinvention to increase adopter comfort and practice level utility, observable benefits early on might have implications on valuation of innovation. Adopter has useful traits and found meaning in offering testing.</p>

The aim with this approach was to develop case studies that demonstrated key dimensions of the process of diffusion and assimilation in RHIVA2. The autoethnographic method was called upon alongside the sampling frame and in the writing up of cases to synthesise the findings and develop a rich picture of key events. This shed light on the process of implementation in the four practices.

## 9.4 Findings

Analysis revealed that the most pertinent aspects of the model were adopter characteristics, system antecedents and readiness for innovation along with the implementation and assimilation process. I will now describe the findings.



### *Findings common to all four case study sites*

Despite the divergence in innovation adoption between the cases, there were some universal findings, particularly in relation to the innovation itself. Informants from all four sites perceived a relative advantage in the innovation. Rapid HIV testing as a part of the new patient health check in general practice was seen to be advantageous as compared to regular practice. This relative advantage can be related to the a) rapidity, b) accessibility, and c) patient comfort.

‘Patient theory of mind’ was also a common finding, demonstrating a triadic dynamic between the innovation, the provider and the patient.

#### *Rapidity*

Providers reported enjoying the rapidity of the test. They also reported this as seen as positive by patients. The rapid test provides a result in one minute, meaning it can be incorporated into the new patient health check and other short consultations. To obtain results from venous testing (usual practice in primary care) requires waiting for a minimum of two days for results. The quick and actionable results of the rapid test mean less waiting and administration and may mean a reduction in loss to follow up of patients. A nurse describes patient reactions to the test:

‘Interviewer: Do you like doing the testing?’

Nurse: Actually, yes, I do.

Interviewer: What do you like about it?

Nurse: I like the fact that people are so impressed by it.

Interviewer: By how fast it is?

Nurse: Not just that, it’s the fact that they get an instant result. And if they’re worried about it then that’s very gratifying for both me and them.’ (Nurse, practice B)

The speed in which the test results are available (one minute) can also be beneficial as compared to what is often a two day plus wait for venous test results. Patients enjoy receiving their result instantly and providers report satisfaction in being able to provide this information quickly.

## *Accessibility*

Placing the rapid HIV test within the new patient health check in an opt-out manner allowed for those unwilling or unconcerned by HIV testing to easily access a test. They felt this meant patients who would not have otherwise been tested agreed to testing. This was also borne out in interviews with patients testing positive through rapid testing within the new patient health check (See Chapter 11). The test does not require a phlebotomist to perform it and so is delivered by a greater range of health care professionals, meaning it can be more easily included in the new patient health check. The HCA describes why she likes offering rapid testing in the quote below:

‘Interviewer: Do you think it’s a good idea to test it in that way?’

HCA: Yes, 100%.

Interviewer: How come?’

HCA: Because most people don’t even think about it at all. They could go on their whole lives not thinking about it and people are quite – I don’t know if ‘ignorant’ is the right word to use. If you offer somebody at a consultation on a one on one an HIV test they might get a bit offended. But this way if you’re saying it’s something that we’re doing at this point in our practice, as a new patient joining us it’s offered randomly, it just gives people a chance to think about if they do want it. If they decline then at least they can come back and say, “You know, I was offered this test and yes, I would like to have it done.” Because people don’t even think about it. So yes, I think it’s a very good idea.’ (HCA, practice C)

Additionally, it meant a significant reduction in pre and post-test counselling, particularly when compared to historical approaches to HIV testing and counselling, as discussed in Part 1. For some patients and providers, the need for a sexual history taking can be a deterrent for testing. Providers found this streamlined testing protocol beneficial to the consultation and in some cases reported greater comfort by patients in not needing to disclose reasons for wanting testing but desiring a test. In other instances, the offer of a rapid HIV test during a new registration meant that an entry point was provided into a discussion or request for more sexual health services. A nurse describes why this form of testing is more accessible:

‘I think it is okay because you know, is not many people who likes going to the GUM clinic. They don’t go unless they are worried about something. But this rapid HIV test, offering it at the time they register, I think is very good. It is more accessible. It is more accessible to patients.’ (Nurse, practice A)

### *Patient comfort*

Providers believed that offering rapid HIV testing for new registrants in general practice made sense and was advantageous in that it allowed more privacy for patients than specialised sexual health centres. Others providers found it an important way of normalising and de-stigmatising HIV testing. A nurse and healthcare assistant from a RHIVA2 intervention practice describe their views below:

‘Nurse: This is a very interesting thing. It is. Like it does make a difference. It does make a difference to patients like because then they get to know what stage they are. And it’s easier access, quick results, instant results. It saves them more time.

HCA: And people who would be really unlikely to go to a clinic because when something’s a stigma then it’s very hard for people to be involved because they would be part of that, you know, that group. So someone – I mean this testing for me means anyone could come in and have it done, a housewife who wouldn’t want to be seen dead in the sexual health clinic. So this test caters for everybody.

Nurse: Even ethnic minorities because in some groups like especially in Asian groups they all think okay. If another Asian person sees me in a sexual health screening and if I know them and you know.

HCA: Anybody because it’s a broad thing really. So having this test in the surgery I think it’s a brilliant thing and it should get more advertised.’ (Nurse and HCA, non-case study practice)

In sum, providers viewed the innovation positively with cited reasons including speed, accessibility and patient comfort.

### *Patient ‘theory of mind’*

Another crosscutting finding related to how providers tended to interact with innovation. As providers described their experiences of rapid testing they reported significant reflections on their perception of patient reactions and feelings and how these perceptions of patient interiority was a key aspect of the testing consultation. Throughout the interviews this patient ‘theory of mind’ was a prominent theme and clearly patterned provider impressions. Many of the models and assumptions implicit in theories of the diffusion of innovations imply a dyadic relationship between an innovation and a single adopter. What was apparent in the data was how providers considered rapid testing in primary care as a triadic interaction between a provider (the adopter), a patient and the test (the innovation). Figure 8 represents

this relationship, the arrows represent the projections of the patient and the provider onto each other and the test device.

**Figure 8.** A visual representation of the triadic relationship between the provider, the patient and the INSTI test.



Greenhalgh et al. acknowledge that greater research and theoretical development is required on the psychological aspects of the diffusion of innovations and that many lessons may be drawn from cognitive and social psychology (Greenhalgh et al., 2004). A health care assistant describes how she considered the views of her patients about testing in the quote below:

‘When we did the training, we were sort of told, with the reactive result, you are to leave the room and get a doctor. I haven’t had to do that yet, but I don’t know how that would make the patient feel, if I am just getting up and walking out.... I mean, I don’t think it was as abrupt as all that in the training.... I don’t know how people feel about that, but obviously something is going on.... Would I just make them more nervous?’ (HCA, non-case study practice)

This ‘theory of mind’ regarding the patient entered the provider calculus and was an overarching finding across the case studies. This finding is an underdeveloped aspect of the diffusion of innovations model, which precludes a more nuanced discussion of the health care consultation, the role of the patient and the impact of new innovations within it.

## 9.5 Findings

I will now introduce a discussion of four practices to demonstrate the findings.

### *Practice A*

Practice A was selected due to their high offer of rapid and serology HIV tests during the trial period (see the upper right quadrant on Figure 6).

**Table 9. RHIVA2 trial performance data for practice A**

<b>Practice A</b>	
<b><i>Practice Size</i></b>	Large >7000 registrants
<b><i>Total serology tests offered in the trial period</i></b>	301 serology tests performed
<b><i>Total rapid tests offered and performed in the trial period</i></b>	1258 rapid tests performed 2039 rapid tests offered
<b><i>Decline rate</i></b>	42% of rapid tests declined
<b><i>Rapid HIV testing detection</i></b>	1 case of HIV was detected through rapid testing
<b><i>Rank amongst other intervention practices</i></b>	Highest number of rapid tests offered of all intervention practices. Decline rate was low compared with other practices.

Practice A implemented the rapid testing intervention very successfully, offering more rapid tests than any other practice with a comparatively low decline rate. One case of HIV was detected via rapid HIV testing. Effective implementation of the test appeared to be the result of key system antecedents for innovation, high system readiness for the rapid test, as well as a smooth implementation process and strong adopter factors among front-line staff (see Table 7).

Practice A is a large and busy practice. It is mature and well organised with a clear differentiation of functions and staff roles as well as good managerial relations. For example the practice nurse and HCA had been with the practice for some time. They felt their roles were clear, and they understood who should be called upon and at what stage if a test was reactive. Both expressed the importance of GPs in making diagnoses both for the patient and their own comfort in offering tests. If needed, they sought information and clarification from senior staff:

‘I’ve had a couple of patients said that they didn’t want the test at the time I offered it, in the new patient health check, but is it okay if I go away, think about it, and then maybe come back, and I’ve said well, you know, this is something that we offer now, if you come back then I’d have to question that with the Doctor as to whether you can have it as a, you know, fully registered patient. I’ve spoken, I did speak to a Doctor actually, and they said that it would be okay if they hadn’t been registered too far down the line.’ (HCA, Practice A)

Junior practice staff were mentored by more senior staff, providing both pastoral support and opportunities for individual and team learning which links to one of the diffusion of innovations key constructs of *absorptive capacity*. Due to regular meetings and the provision of feedback to practice staff there appeared to be opportunities to integrate new knowledge and reflect on work practices. Practice A showed interest in the monitoring of progress and the study’s overall performance, often asking how they rated in relation to other trial practices.

Leadership, organisation and communication appeared to be strong factors in practice A. For example, a lead was assigned for the intervention and provided support to junior staff tasked with delivery. While roles were well differentiated, support was provided promptly when required.

Interviewer: But you’ve had a reactive?

Nurse: That was early one.

HCA: Yeah.

Nurse: Trying to, I’m trying to recall it.

Interviewer: Okay.

Nurse: As to what, as what I actually said. I remember I sent a screen message to (GP A) and I, I think I just said something like oh, that I needed the Doctor to verify the result, and that I needed him to look at it. I think it was something like, that, it’s such a long time ago now, and then (GP B) came in and I had a chat with him and we did the blood test, gave him some information, and I think (GP A) said that he would be in contact with him.’ (Nurse and HCA, practice A)

Key staff in practice A believed that offering patients testing in this way improved their service, inducing a sense of pride and value in their work. This can be seen in the quote from 2 providers of rapid testing below:

‘Nurse: Yeah, I think, the impression I get is that they think that we’re been quite thorough and that we’re, you know, so I think it, I think it promotes us

HCA: That we’re very organised, well she said I’m very organised and thorough.

Nurse: Yeah that we care and that we’re offering a good service.’

(Nurse and HCA, practice A)

Positive views on the intervention by staff tasked with delivering it may have impacted the quick adoption of testing in practice A. The staff member also appeared well supported and was the only one of the 16 practices interviewed who did not mention time constraints. These findings may have indicated that there was better ‘innovation-system fit’ in the practice and that ‘slack resources’ were available (see Table 7). Another finding which may have bearing on the quick adoption of rapid testing by practice A, identified in the model as ‘observability’, is how fairly early in the trial the practice identified a case of HIV through rapid testing. This tangible and demonstrable experience that the intervention does produce the intended results may have gone some way in motivating the practice to continue testing.

The innovation of rapid HIV testing as part of the new patient health check was well adopted in practice A and there was a good innovation-system fit. Key front-line staff believed in the value of the intervention and had early evidence of its effectiveness. Practice A was a setting where key system antecedents for innovation were present, including a large formal structure, a strong absorptive capacity for new knowledge and a readiness for change. Slack resources appeared available and positive work place relations with role differentiation, feedback loops, knowledge sharing and reflexive practice dimensions already in operation enhanced the potential for the intervention to be successfully adopted. There was no detectable intra-practice opposition to the intervention and due to the high-quality data capture, good communication and strong leadership there was less likelihood for problems to arise.

### ***Practice B***

Practice B was selected due to its high offer of rapid tests without much change in the offer of serology testing (see the upper left quadrant on Figure 6). There were moderate system

antecedents, high performing front line staff and internal synergies that facilitated the adoption of the new innovation.

**Table 10. RHIVA2 trial performance data for practice B**

<b>Practice B</b>	
<b><i>Practice Size</i></b>	Medium >5000
<b><i>Total serology tests offered in the trial period</i></b>	101 serology tests performed
<b><i>Total rapid tests offered and performed in the trial period</i></b>	556 rapid tests performed 870 rapid tests offered
<b><i>Decline rate</i></b>	37% of rapid tests declined
<b><i>Rapid HIV testing detection</i></b>	4 cases of HIV were detected through rapid testing
<b><i>Rank amongst other intervention practices</i></b>	3 <sup>rd</sup> highest number of rapid tests performed of all intervention practices. Highest number of cases of HIV detected through rapid testing. One of the lowest decline rates of all intervention practices.

Practice B performed well throughout RHIVA2, offering a high number of tests and assimilating testing into the new patient health check. The practice is small-to-medium in size with relatively low turn-over of patients and new registrants. Despite this, practice B diagnosed the most cases of HIV through rapid testing, twice as many as any other intervention practice. There was a high number of tests offered ( $n = 870$ ) and the rate of tests declined was low (36 %). This practice had high rapid testing and low serology testing, and was in the bottom five of the 40 participating practices in RHIVA2 (fourth amongst the 40 with 0.66/1000 serological testing rate during the trial period, and 2.07/1000 prior to the trial,



respectively). Various factors at both the organisational and individual levels may help explain the success of the practice in delivering rapid testing.

Practice B demonstrated moderate system antecedents and readiness for innovation. A well-organised and harmonious practice, there was a clear division of roles for staff and staff tended to hold their colleagues in good esteem. The practice had a calm feel and compared to many of the practices visited throughout the trial there appeared to be a strong capacity for new knowledge and receptivity to change. There appeared to be pre-existing willingness to learn and a context in which new knowledge could be incorporated. The practice appeared concerned about supporting patients beyond their immediate medical needs, a finding also demonstrated by the longer time allocations for patient visits such as the new patient health check. An example of intra-practice harmony was demonstrated when the lead nurse was concerned about the misinterpretation of a rapid test. She discussed her concern with the GP and the two developed a plan together, without reproach, with the patient's safety in mind. This example may also point to a practice with a risk-taking climate and positive managerial relations, which are facilitators in the uptake of new innovations. In the quote below, the lead nurse describes this example:

‘Respondent: There was one which did ... that was indeterminate. There was ... you know, the pots. It was ... it was supposed to be non-reactive, but inside that pot it was like a line.

Interviewer: Okay. Right. Just a straight line.

Respondent: And when I told the doctor, he say, probably ... no, not the doctor; the lady that came the other day. He said probably it is damaged or something like that. But I told Doctor A, and he said I should call the patient back, you know. So, we call the patient back, and I explain, even to the patient as well, that this result, it doesn't mean you have HIV now, but it might be one thing or the other that is making the ... you know, the test to being invalid. So ... and she decided ... she came back.

Interviewer: Had another test.

Respondent: Yes. And it was non-reactive.’ (Nurse, practice B)

The intervention was adopted quickly and the lead nurse, who was tasked with providing all new patient health checks, was enthusiastic about the innovation and saw the value of the trial. That a single nurse undertook all new registration checks and was provided 30 minutes to perform it was unusual as compared to other participating practices in the trial. In addition, she was allocated her own dedicated consultation room and was a full time employee. She

appeared well respected by both staff and patients. This was recounted in stories she would tell about her clinical interactions. She was patient-centred and saw HIV testing as an ethical imperative and an important service for the wider population. She describes these sentiments in the quote below:

‘I think I just like doing it because it is good. When you think about the end result, is good. It makes you feel you have done something good as well. At least for somebody who doesn’t know that is positive and is not, because although the news of being positive, it has a lot of effect on them, but after counselling.... But I believe it will prevent other people as well, or protect other people. Either prevent or protect from catching it because if it is known, then the patient can take precaution not to infect other people.’ (Nurse, practice B)

When visiting the practice and speaking with the lead nurse it became apparent that she managed to ‘reinvent’ the test and the algorithm to suit her workplace practices. She did this without compromising the delivery of the intervention and therefore maintained fidelity to the trial. She was concerned by the potential effect of a reactive result on the patient undergoing testing and so began to perform the definitive aspect of the test away from the patient’s view. This was an adaptation that was not in the original training. Additionally, she did not disclose to the patient that the test took one minute. She took these steps to give herself some space to interpret the result and plan how she would share it with the patient, demonstrating reflection on her practice and concern for her patients. She describes this in the quote below:

‘Interviewer: Yes. How did you feel the first time you saw a reactive?  
Nurse: I was ... but I was looking, but he wasn’t looking at me.  
Interviewer: Yes, because you do it on that side of the room.  
Nurse: Yes. On that side. So he was sitting down there, so ... but he was looking at me as well. But because I was facing that side, he couldn’t see my face.’ (Nurse, practice B)

Another adaptation, which may reflect positive work place relations, trust in the lead nurse and aspects of reinvention, was how the GP would refer patients to this nurse for rapid testing. This included patients who were not newly registering. The nurse reported that at least one patient for whom the possibility of HIV infection was being considered was persuaded to have the rapid test due to their dislike of more invasive serology testing. As in practice A, a positive HIV diagnosis through rapid testing was made early in the trial, reinforcing staff confidence in the test.

Numerous system antecedents were present in practice B. There was high readiness for innovation along with pre-existing facilitating factors for implementation. The role of the lead nurse as a keen and committed front line staff member was crucial. What was also theoretically important and noteworthy about practice B is the way that the facilitating factors combined on site to enable a smooth and effective roll out of rapid testing. The combination of practice level factors such as the specified role, space and time allocation for the new patient health check combined with the patient-centred and personally motivated lead nurse, along with her sensibility to reinvent the test to fit her personal work practices greatly impacted on the level of innovation adoption. The practice appeared calm and to possess a culture of openness and improvement that supported the embedding of the intervention. Inter-collegial respect was evident in the description of how patient cases were managed as well as in how problems were solved. The lead nurse's competence was recognised which facilitated testing and the flow of patients towards the rapid test. Elements conducive to the adoption of new innovations were able to build upon themselves in a synergistic manner.

### ***Practice C***

Practice C did not perform many rapid HIV tests in the course of RHIVA2. The practice had low system antecedents for innovation and front line staff who were reluctant to take on rapid testing and implement the new innovation. Practice C was chosen for their low offer of both rapid and serology HIV tests (see Figure 6 lower right quadrant).

**Table 11. RHIVA2 trial performance data for practice C**

<b>Practice C</b>	
<b><i>Practice Size</i></b>	Medium >5000
<b><i>Total serology tests offered in the trial period</i></b>	59 serology tests performed
<b><i>Total rapid tests offered and performed in the trial period</i></b>	36 rapid tests performed 73 rapid tests offered
<b><i>Decline rate</i></b>	50% of rapid tests declined
<b><i>Rapid HIV testing detection</i></b>	No cases of HIV detected through rapid testing.
<b><i>Rank amongst other intervention practices</i></b>	Low serology and low rapid testing throughout the trial period. One of the poorest all around performers in the trial.

Practice C was a low performing practice. It took a few months for the practice to offer their first rapid test and there was never full routinisation of testing, despite encouragement by the research team and some members of the practice staff. I visited the practice to ‘troubleshoot’, including one occasion where there was a request for more tests despite the electronic system indicating not a single test had been performed at the practice. Upon delivering new test kits I realised that practice staff were unaware where the test kits were being stored and that the box remained unopened. There was a low HIV serology testing rate prior to and throughout the trial. Individual and practice level factors appeared to combine and make for a practice unable to effectively adopt a new innovation such as rapid testing.

System antecedents for innovation appeared to be low in practice C. A small practice, it comprised three GPs, one nurse and one HCA (both of whom undertook new registration

checks), one practice manager and two receptionists. Located within a large building housing multiple surgeries, practice C, always seemed crowded and very busy.

The practice showed little interest in, or gave time to accommodate, new innovations, and there were few resources (human or financial) available to invest in new projects. Overall, the practice appeared to find a new service model difficult to integrate into business as usual. There was frustration expressed with changing NHS policy and guidance as well as broader changes in health care culture. A low absorptive capacity for new knowledge was also evident. One of the doctors, for example, asked the research team how to access information and register for GP training courses unrelated to the intervention, suggesting that this individual found locating and navigating information difficult. Significantly, practice staff did not perceive a great need for HIV testing in the borough, suggesting that there was little, if any, tension for change. The nurse described herself as ‘overstretched’. She gave the impression of barely being able to complete her existing work and having almost no personal capacity for additional tasks:

‘[The rapid HIV test] really is not a problem. It’s just, you know, having the time. I mean, often I get to the end of a morning, and I feel like a rag.’ (Nurse, practice C)

Considering the demand upon practice C and the sense among practice staff of being in a constant state of rush it is understandable that practice C never fully routinised the intervention. The majority of patients having new patient health checks were not offered the test and no cases of HIV were detected with rapid testing. As a result, observability of the effect of the intervention never came into view. As the member of the research team most frequently visiting the practice, I had the sense that practice C viewed rapid testing as a research activity and an ‘add-on’ but not as a part of routine practice.

In contrast to practice B, an issue of key importance in practice C was reluctance and compatibility between the test and the values of the HCA, who was the front-line staff person principally tasked with delivering testing. The HCA appeared uncomfortable with HIV and with the test, expressing reluctance in the training session. As testing data is aggregated per practice at the point of collection it is unclear if the HCA offered any rapid tests during the

trial period. A nurse, who joined the practice at a later stage in the trial and who was more comfortable with the test, describes her frustrations in trying to improve the uptake of rapid testing in the quote below:

‘I don’t have any problem with doing [the rapid HIV test]; the actual doing of the tests is straightforward. My colleague who should be doing them as well hasn’t done one. I don’t know. I went through it with her again a while ago; I don’t know, two or three weeks back I went through it again with her to remind her how to do it. And I do it whenever I can, but my problem is time.... I don’t know if it’s a religious thing, maybe [explanation of perceived religious views of colleague]. I don’t know if it’s something to do with that. But she’s a health care assistant; she’s not a nurse. That’s a difference as well.’ (Nurse, practice C)

The nurse emphasises professionalism as an important aspect of delivering testing, beyond the technical capabilities. She sees testing as a professional interaction that calls upon her experience with patients and training as a nurse. While the test might seem technically simple, it is testing for HIV, an infection that remains highly stigmatised, potentially adding complexity and emotionality to testing. My interview with the nurse revealed that she was proud of her patient-centred approach and described any success she herself had with testing as down to her ‘way’ with patients. HIV remains a stigmatised condition, and the line between a screening test and a diagnostic test can be fine, particularly in the case of the test used in the trial, which may be interpreted by patients as well as providers (two dots as a reactive result, one dot as a non-reactive result). It may have been that reluctance to offer rapid testing relates to the need to provide immediate feedback regarding test results. Whereas GPs are called upon to share test reactive results, HCAs and nurses expressed significant concern about managing reactive results and patient reactions as well as the interval between the test and calling upon the GP. This may have been a factor in the HCA’s reluctance to test. The nurse, though personally motivated and more professionally experienced, had only limited opportunity to offer rapid HIV testing, as most new patient health checks were performed by the HCA.

The nurse discussed felt responsible for trying to improve the testing performance of the HCA. She reported raising the issue with her superiors with no avail. In general, the practice seemed reluctant to discuss testing with the HCA, citing numerous reasons why they thought

the intervention may not suit her. Whereas practices A and B demonstrated good managerial relations and a problem solving ethos, the approach in practice C was less involved and there was a sense of resistance to change.

The frustration of the practice nurse is understandable as she appeared to make numerous efforts to increase the offer of testing. For example, she showed creativity in ‘reinventing’ the finger-prick aspect of the test. (*“As long as I get a decent drop of blood, just occasionally people don’t bleed terribly well. I don’t like the finger-pricker they give with it. I tend to use my ones.... They’re a bit more gentle.”*) Despite this, as she was not tasked with delivering the majority of new patient health checks her efforts did not translate to much of an increase in the testing numbers. The practice’s low absorptive capacity was evident in the lack of encouragement for skills sharing and communication, with the result that her local adaptations and reinventions were not shared with other staff and, notably, were not adopted by the front-line staff with the most responsibility to offer testing.

Practice C did not have many attributes that would enable the effective adoption of a service-level innovation. The key staff member on which the implementation of the test depended was personally reluctant, and this stance persisted despite efforts from colleagues and the research team. The lead nurse, who was motivated, demonstrated local reinvention and valued the intervention, but she was not able to overcome other more hindering contextual factors such as poor system readiness and few system antecedents for innovation. Progress was further hindered by what appeared to be reluctance related to the focus of the intervention, HIV testing, and very little tension for change.

### ***Practice D***

Practice D was chosen due to the low offer of rapid HIV tests and high offer of HIV serology tests (see Figure 6 lower left quadrant).

**Table 12. RHIVA2 trial performance data for practice D**

<b>Practice D</b>	
<b><i>Practice Size</i></b>	Large Practice <10,000
<b><i>Total serology tests offered in the trial period</i></b>	696 serology tests performed
<b><i>Total rapid tests offered and performed in the trial period</i></b>	302 rapid tests performed 557 rapid tests offered
<b><i>Decline rate</i></b>	54% of rapid tests declined
<b><i>Rapid HIV testing detection</i></b>	No cases of HIV detected through rapid testing. High level of missed opportunities for testing.
<b><i>Rank amongst other intervention practices</i></b>	Highest number of serology tests offered in the borough. Low rates of offer for rapid testing considering size and number of eligible patients. Moderate to high decline rate. No HIV detected through rapid testing.

Despite the expectation of practice D being a high-performer in RHIVA2, practice D struggled to implement rapid HIV testing. While the figures in the table above demonstrate that a number of rapid HIV tests were offered during the trial period, considering that practice D was one of the largest practices in the trial, with a demonstrated interest and capacity in HIV testing and a high number of newly registering patients, the offer of HIV rapid tests was low. The missed opportunities appeared to reflect a number of practice level factors and analysis demonstrates that while there were periods of increased testing, the intervention was not ever truly adopted and routinised.

Practice D is large and diverse and includes a large mix of staff including numerous part time and locum staff, junior doctors, GPs with special interests, numerous nurses and HCAs and



over 10 receptionists and administrators. A lack of time and slack resource meant that the practice was constantly busy and conversations with administrative staff revealed how this placed pressure on intra-practice relations and service delivery.

The striking contrast between the very high HIV serology rates but very low rapid testing rates may be related to my finding that there were two distinct work cultures within the practice. Many of the GPs were highly qualified with some involved in community-based projects including work in sexual health. As mentioned, the practice had a very high serology testing rate prior and throughout the trial. However, the nurses, health care assistants and other practice staff appeared to have little involvement in these activities. Knowledge appeared to circulate poorly throughout the practice perhaps due to the large number of staff with differing working arrangements. Some staff worked part-time and appeared to have a very task-oriented attitude toward their work (i.e., they came to work, completed what was expected of them and went home). There appeared to be relational tensions between some staff in the practice that affected the implementation of the study protocol. For example, reception staff had been asked by the lead nurse to hand out leaflets about the study to patients at the reception desk, but this did not always happen. I was asked to speak to the reception staff and describe the study and the role of the patient information sheets to help mediate the issue.

Despite feeling overstretched the staff involved in the trial appeared enthusiastic about rapid testing. Throughout the trial and expressed in interviews however was the sense that rapid testing was an additional task and as it was not assigned to important practice indicators it was an easy thing to 'leave off the list'. So while the GPs saw the value of participating in research other practice priorities trumped and it was unclear that the value placed on the intervention by senior staff was ever made clear to front line deliverers of the intervention. The inconsistent pattern of rapid testing across the trial period is likely a result of practice deadlines and occasional intervention from senior GPs aiming to increase testing. This may have been as a result of our study team intermittently reporting results to the senior GPs. So while perhaps reluctant opponents of the intervention, the front-line staff were unable to support rapid testing in a routinised and consistent manner. The HCA explains:

'But because it was coming up to the end of the financial year and everyone had to tally up QOF points for diabetes and these and this and that, it took priority. If people had come in, obviously if there were new patients, we wouldn't turn anybody away, but we were phoning up and pre-booking patients to come in for their diabs or their foot checks or their blood pressure. And because I'm only now doing 3 days a week, I literally split sessions between here and (another practice). I do here three sessions and there three sessions. So, when I am here, they get me to do loads of ECGs and different other things, and then when I'm there, I'm doing things over there that they need doing.' (HCA, practice D)

Unusually, one nurse involved in delivering rapid testing also struggled with the technical aspects of the test. Citing an issue with mobility, she found the test difficult to unwrap and use, meaning that it took longer to perform and was a source of frustration. She indicated that over time her offer of testing reduced as a result. While all the front-line staff in practice D expressed enthusiasm for testing and saw value in the study it appeared that a convergence of factors meant that testing was never fully implemented. A lack of slack resources, oversight, consistency of role and poor communication were strong factors hindering adoption.

These organisation-level factors significantly overshadowed other, more positive elements of this practice in relation to HIV testing, including the perceived relative advantage of the rapid test in comparison with the widely used serological testing, and the compatibility of the test with the values and goals of the practice. It may also have been that despite the obvious relative advantage of rapid testing the practice had on-going and significant serology testing, reducing the tension for change.

While practice D was a large and enthusiastic practice with an interest in HIV and a significant number of newly registering patients, adoption was impeded by various factors. Structural, capacity-related and cultural factors along with individual adopter traits, combined with poor organisation and limited slack resources, appeared most crucial in hindering implementation.

## 9.6 Summary of findings

The process evaluation undertaken here combined with an analysis using the Greenhalgh et al. model of the diffusion of innovations in health care organisations has demonstrated a fit between the method, the theory and the data. The approach was able to elicit a nuanced discussion of findings that goes some way in explaining the variation of rapid testing in RHIVA2 intervention practices. Six dimensions of the Greenhalgh et al. model of the diffusion of innovations were found to be key. I will now summarise each.

### *Innovation attributes*

Attributes comprising the section of the model related to the innovation itself were generally positive across intervention practices. The relative advantage of the test as compared to existing HIV testing practices was an overarching finding. Practices reported finding the speed and portability of the test as generally positive. This finding links to the aforementioned overarching finding related to ‘patient theory of mind’, as provider views appeared largely informed by the positive review the test received from patients.

### *System antecedents for innovation*

Practices with strong system antecedents appeared better able to adopt the innovation. This was largely related to how practice staff were organised and treated. More formally organised practices with clearly differentiated roles and senior support appeared more able to implement the innovation. This may relate to the greater provision of slack resources, support and feedback as well as better communication. These positive managerial relations, role comfort and ability to access support when required influenced practice performance.

### *System readiness for innovation*

If practices saw a role and need for increased HIV testing, known in the model as ‘tension for change’ there appeared to be greater enthusiasm for the adoption of testing. If a well-

organised and consistent new patient health check was present in the practice, then the mechanism for delivering rapid testing was more stable and facilitated implementation. If regular staff were provided with dedicated time, support and resource to add this additional task to their new patient health check, such as in practice A, then the intervention appeared more likely to be routinised.

### *Adopter characteristics*

As seen in both practice A and B, adopters who are personally motivated, see the broader value of the innovation and find it easy to use are more likely to implement. In practice A, the nurse felt she was personally helping her community, while in practice B staff reported feeling that the innovation improved the community perception of the practice as a whole. However, as seen in practice D, even if staff are individually motivated, this may not overcome other organisational factors.

### *The implementation process*

The process of implementing the innovation was facilitated by an involved approach from senior staff (practice A) or the devolution of the task to highly competent and stable staff members (practice B). If practices assumed implementation would take place without practice level consideration and tailoring post trial GP training session (practice C), there appeared to be less likelihood of the innovation being implemented. If feedback and support were not provided throughout the early stages of implementation, practices were less likely to adopt the innovation. Implementation was more likely when stable, dedicated staff provided the new patient health checks, and slack resource was generally more available in the practice.

### *Re-invention and local customisation*

Some staff demonstrated small local adaptations to testing. This ability to tinker with the ‘soft-periphery’ aspects of the innovation appeared key to adopter comfort and ease in offering testing. In some cases, adaptations were as simple as using a different pipette that

was more technically simple (practice C), in other cases, this meant accounting for the patient experience (practice B). While this factor alone may not have been enough to overcome a general lack of practice attributes in some cases, this aspect appeared important and demonstrated a willingness and ownership toward the innovation that may be key in an effective implementation process.

## **9.7 Discussion**

### *Positive and negative synergies*

An important finding, and consideration in articulating the findings, is how various attributes facilitate, enable, depend upon and converge with other attributes creating both positive and negative synergies for implementation. In the case of practice B for example, the personally motivated nurse was enabled by adequate time, space and support to deliver a consistent new patient health check. That the practice was organised in this way reflects broader structural system antecedents. Together this allowed her to offer more tests which led to greater detection and significant observability. Similar descriptions of compounding attributes can be described in all case studies resulting in the variable adoption success. This may also be evidence of the ‘interlocking interactions’ described by Dopson et al., where the characteristics of contexts, communities and practices interact to enable innovation or not (2002). What is described here reinforces the argument that there is no singular or fail-proof method of ensuring implementation. It may be unhelpful to conceptualise of innovations as discrete entities to be added on to existing structures. Innovation adoption is likely best conceived of as a process comprised of numerous formal and informal decisions at multiple levels (2010).

### *Innovation specificity*

While the model of the diffusion of innovations in healthcare settings explores attitudes towards the innovation by organisations and adopters, it was unclear how the ‘subject’ of the

innovation interacted with the evaluation of feelings about the innovation itself, including the material aspects. It appeared that if a provider had a view of HIV, for example, that was negative, then despite many positive organisational attributes the innovation may never be adopted. This links to the ‘compatibility’ attribute in the diffusion of innovations model and was a finding raised in the aforementioned systematic review, where ‘the specific innovation concerned’ was relevant to the adoption journey (Robert et al., 2010: p. 247). The specificity of HIV patterned many of the provider behaviours, including the adaptations of the nurse in practice B, for example. This also links with the previous discussion on ‘theory of mind’ and the triadic relationship between the test, the patient and the adopter. Considering the patient and the innovation ‘subject’ more explicitly in the theorising of the diffusion of innovations may allow for the capture of additional critical factors related to the implementation process.

### *Routinisation*

Practices who were successful in implementing the rapid HIV test as part of the trial had routinised the innovation not merely by assigning its component tasks to particular staff members but also by encouraging and rewarding those staff for embedding it in the day-to-day work of the practice and linking it to other routines. This crucial distinction between ‘complex intervention as a set of tasks’ and ‘complex intervention as embedded routine’ aligns with Denis et al.’s notion of the ‘hard core’ of a complex intervention (the elements that constitute its ‘fidelity’) and the ‘soft periphery’ which can and must adapt to accommodate it (2002). This further consideration of routinisation as a key processual dimension of adopting new innovations has been the subject of a number of more recent studies (Robert et al., 2010; Greenhalgh, 2008). In RHIVA2 it is possible that practices more quickly able to routinise rapid testing were either previously, or quickly became, more comfortable with the innovation through the proposed benefits of routinisation, such as a reduction in uncertainty and a conferring of stability (Greenhalgh, 2008).

### *Adopter autonomy and innovation as a workplace lever*

Some low-recruiting practices raised concerns about leadership, staff relations, role distributions and possible internal hostilities. It was also obvious to me on a few occasions when visiting intervention practices that such issues were impeding the implementation process. In some cases, the innovation itself appeared as a sort of “bargaining chip”, or further piece of evidence to demonstrate intra-office inequalities and in these cases the behaviour regarding the innovation appeared to have very little to do with the innovation itself but reflected these broader organisational problems. Such issues make the routinisation of innovations extremely difficult, and it may be that sensitive exploration of the system antecedents and key success factors for implementation may allow practices with such ‘risky’ characteristics to be identified in advance of the trial and offered targeted support or even be excluded from the sampling frame. Robert et al., indicated the need for great importance to be ‘placed in the interactions between groups than previous (non-healthcare based) literature predicts’ (2010: p. 247). Their additional finding that the converging of various professional groups in the delivery of new innovations may act as a barrier may also have been evident in the cases described above, where professional understandings, training and experiences influenced provider perceptions about the innovation and their ability to deliver it, such as in practice C (Robert et al., 2010).

What was described above also reflects who makes the decision for the practice to participate in a trial and roll out a new innovation. This aspect was discussed by the forefather of diffusion of innovations work, Everett Rogers and highlighted again in the Robert et al. systematic review (Rogers, 2003; Robert, 2010). Rogers observed that adopting an innovation is optional, collective or authoritarian (2003). Robert et al. described how there is rarely a single instance of adoption, or a predictable lead adopter (2010). It is unclear how the adoption decision was made in RHIVA2 intervention practices but the data reflects that in some cases the approach was authoritarian, where the decision is imposed by more powerful members of the organisation. The collective, where a group decision is made, or individual decision model, where each member opts in or out, may have led to increased implementation. As HCAs were most likely to deliver rapid testing in RHIVA2 and often hold more precarious positions in general practice they generally appeared less likely to

influence organisational decisions and occasionally expressed resentment regarding this during interviews. Authoritarian decisions lead to high rates of initial adoption but also to high levels of front-line resistance, particularly in practices where human resource issues are already present (Rogers, 2003). Ideally, the decision for an organisation to join a trial of a complex intervention should be made collectively and should certainly include the staff whose job it will be to deliver the intervention.

### *The unsurprising role of 'slack resources'*

A more general way to improve the uptake of interventions is to consider the role of slack resources and work with organisations to consider this issue as related to adopting a new intervention. Organisations such as practice B, who had a dedicated consultation room for the lead nurse and a full 30 minutes for each new registration check, obviously had more time and potential for continuity in rolling out the intervention. Conversely, in practice D, key staff were pulled from research projects when other key practice priorities loomed. Working with practices to consider the planning and true costs of implementation may help guard against such issues, perhaps calling on supplementary resources (overtime pay, for example) could be considered.

### *Summary*

In the findings chapter presented above, I used an evidence-based model of the diffusion of health care innovations and applied it to various data emerging from the RHIVA2 trial (quantitative) and interviews with those implementing the intervention (qualitative). To my knowledge, this was the first instance of application for the Greenhalgh et al. model of the diffusion of innovations to a cluster randomised controlled trial. The model proved a useful way to explore the RHIVA2 trial and the trial itself a good way to test the Greenhalgh et al. model through four contrasting practice experiences of testing. In this analysis, the model was applied retrospectively; the potential for the model to be used prospectively will be explored in the discussion. Further work may explore using this approach across multiple



trials, trials of more complex phenomena and with greater theorisation of the triadic relationship between the intervention, the provider and the patient. The findings presented above support the conclusion that there is not, nor can there ever be, a universal implementation model for complex interventions. Site-specific characteristics and realities need to be considered.

In Part 2, the two stories threaded through this thesis converged with differential effects across 20 intervention practices in RHIVA2. The logic of normalisation for HIV, which justifies screening approaches and prioritises the general population, merged with the logic of the pragmatic trial, which aims to evaluate interventions in their context of use. In Part 3 we move to the imagined end point of the RHIVA2 trial, the HIV-positive patient, as detected through rapid HIV testing. The patient body represents another site where the two stories converge. It is here in Part 3 that the logic of the pragmatic trial will come more clearly into view, enabling an in-depth discussion of ontology, experimentation and the impacts of the two logics on individuals and on evidence.

### **PART 3: Experimental end-points: Patient experience and the pragmatic trial**

Having thus far encountered some of the complexity that RHIVA2 engendered in practice, in Part 3 I aim to provide a deeper analysis of the findings and provide insights at the methodological and theoretical level. Through two findings chapters where I consider both RHIVA2 patients testing HIV-positive with the rapid test and the trial results (both conceivable end points in the view of the trial and the policy). I explore how the logic of normalisation is encountered by those testing HIV-positive with rapid testing, and how the logic of the pragmatic trial organises study findings.

Chapter 11 introduces five in-depth patient case studies that describe how the trial became meaningful for each patient, each of whom tested positive for HIV with the first test being a rapid HIV test as part of RHIVA2. I also trace the work of ‘normalisation’ through the patient case studies exploring how this logic patterns patient experiences of HIV testing and diagnosis. Chapter 12 acts as a synthesis of findings from studies at the policy, provider and patient level. This chapter explores the logic of the pragmatic trial explicitly and aims to make a methodological and theoretical contribution and also works as an introduction to the discussion chapter. Through the presentation of two cases, termed ‘ambiguities’, I demonstrate how the pragmatic trial logic occludes much of the productive work of the RHIVA2 trial. I begin with a discussion of some relevant literature from the fields of science and technology studies and anthropology.

## Chapter 10: INNOVATIONS IN PRACTICE: INTRODUCTION TO PART 3

What has become apparent in the collection of the data presented here is how innovations are not straightforward, predictable objects that interact neutrally with individuals and settings. The literature described below encourages the discussion of objects and their interactions with greater complexity.

People survive HIV as a result of innovation and technology. At present there is no real ‘living with HIV’ without HIV treatment. The process of uncovering and then ‘living with’ HIV relies on devices, both material and conceptual. Matter such as blood, tests and monitors, as well as concepts such as the definition of HIV as a series of levels of CD4 counts, viral loads and antibodies, construct our understanding and experience of HIV. We rely on these concepts and tools to make the infection knowable and bearable. This way of approaching HIV represents a disciplinary slant related to Science and Technology Studies (STS), material semiotics and some realms of anthropology. These approaches complicate the view of HIV and screening as presented in the typical biomedical literature and provide productive lenses to consider what was pronounced in the PhD data.

STS researchers take interest in the social processes that produce scientific and technical knowledge and propose that knowledge and technology shapes and is shaped by society (Law, 2004). How this knowledge is positioned as evidential and valid and how it is inscribed in ‘texts, people, machines, images or other forms’ is considered alongside its contestations, transformations and role in relations (Cornell, 2015: p.1). STS draws heavily on actor network theory (ANT), as first developed by Bruno Latour and Michel Callon (Latour, 2005). While the term has been widely interpreted and disputed, Latour describes his work as a science of associations and not only as the science of the social (Latour, 2005).

In his paper ‘*Actor Network Theory and Material Semiotics*’, which I draw largely upon, John Law provides a nuanced discussion of the two concepts. He describes ANT as a part of a

material semiotic approach where ‘entities take form and acquire their attributes as a result of their relations to other entities’ (Law, 1999: p.3). For example, CD4 counts only become markers of HIV level when they are linked through blood tests for HIV antibodies. HIV diagnosis requires the choreography of concepts and materials into a particular relationship within a particular network to make HIV ‘real’. ANT is often classified as a constructivist approach to knowledge and reality, though others have called it ‘performative’ because of its emphasis on actors and action rather than talk and text (see quote below). In ANT, there is not one knowable truth of the world ‘out there’ and the realities of people and things are constructed through interaction. ANT is outlined by Law as:

‘a disparate family of material-semiotic tools, sensibilities and methods of analysis that treat everything in the social and natural worlds as a continuously generated effect of the webs of relations within which they are located. It assumes nothing has reality or form outside the enactment of those relations. Its studies explore and characterize the webs and the practices that carry them. Like other material-semiotic approaches, the actor-network approach thus describes the enactment of materiality and discursively heterogeneous relations that produce and reshuffle all kinds of actors including objects, subjects, human beings, machines, animals, ‘nature’, ideas, organisations, inequalities, scale and sizes and geographical arrangements’ (Law 2009: p.2).

He goes on to further nuance the term. Law indicates the inability to describe ANT accurately in the abstract as it requires empirical case studies to be known and understood. Law articulates ANT is not a theory per se due to its descriptive rather than explanatory role. He highlights ANT’s lack of status as a single entity or approach before finally defining ANT as ‘empirical post-modernism’. ANT is best understood, according to Law as a ‘toolkit for telling interesting stories’, a ‘sensibility to the messy practices of relationality and materiality of the world’ and a ‘diaspora that overlaps with other intellectual traditions’ (Law, 2009: p.2).

The description is not straightforward, and fitting to the discipline, Law rejects having the ‘objectivity of an overall view’ (Law, 2009: p.3). Helpfully Law continues to describe important developments in the field, including ‘enactment’, ‘multiplicity’, ‘fluidity’, ‘realities and goods’ and finally ‘ontological politics’. Some of these themes have already been present in the thesis and others will be discussed in relation to the findings presented in the coming

chapters. I will now briefly describe enactment and multiplicity before moving onto a discussion of paradox and non-coherence.

### **10.1 Enactment and multiplicity**

Law discusses the importance of ‘enacting’ and performing practices to bring realities into being. He describes this as a slight move away from constructivism as this mode of thought posits a primary constructor of realities (2009). Law’s proposition is that a focus on enactment demonstrates the ways beings and non-beings play a relational part of what emerges as the real, and it is through these performances that these realities take shape. He calls on Latour’s exploration of pasteurisation in France and Garcia-Parpet’s work on the performance of strawberry markets to illustrate his point (Garcia- Parpet, 2007; Law, 2009). Work by Annemarie Mol also further demonstrates ‘enactment’ and an exploration of her work on medical practices forms part of the intellectual ‘diaspora’ Law refers to (Mol, 2002; Mol, 2008; Law, 2004).

In *The Body Multiple*, Mol’s ‘praxiography’ of atherosclerosis, she traces the disease throughout various spaces in the hospital setting and discovers a multiplicity of reality in practice. Proposing this as ‘empirical philosophy’, Mol tackles ontology, social theory and method (2002). She explores how reality is constantly being enacted through practice and how there is a merging of subject and object in an ongoing ontological process of reality shaping, demonstrating a multiplicity of disease and medicine and highlighting the social, collaborative and complex ways in which we ‘enact’ medical practices and technologies (2002). Lisa Blackman summarises Mol’s *The Body Multiple* in the quote below:

‘The aim of Mol’s research which focuses on how arteriosclerosis is enacted is to ‘study the multiplication of a single disease and the coordination of this multitude into singularity’ (2002:82) The coordination of multiple objects so that they ‘hang together’ is not due to the discreteness of the object itself, but rather to the strategies and practices which distribute the objects across different sites, locations, activities, experts and interventions.’ (Blackman, 2008: p.125)

Enactment is key to Mol's contribution on multiplicity. Through tracing atherosclerosis through the hospital she uncovers and then proposes that there are multiple 'atheroscleroses' and that we should not think of disease as a singular object but as multiple, dependent upon the coordination of relations in which it is enacted. For example, under the microscope it is one thing, for a patient another. In describing this assertion, Mol states:

'If practice becomes our entrance into the world, ontology is no longer a monist whole. Ontology-in-practice is multiple. Objects that are enacted cannot be aligned from small to big, from simple to complex. Their relations are the intricate ones that we find between practices. Instead of being piled up in a pyramid, they rather relate like the pages in a sketch book. Each new page may yield a different image, made with a different technique and in as far as a scale is recognizable, it may again, each time, be a different one. There is no fixed point of comparison.' (Mol, 2002: p.157)

As reality is enacted through practice it multiplies. Not infinitely and randomly however, but as 'more than one but less than many', it is 'manifoldness but not plurality', the practices enacting this multiplicity somehow hang together and often coordinate or compete to allow for decision making (Mol, 2002).

In another important work, briefly mentioned in the Introduction, *The Logic of Care*, Mol continues to explore medical practice through the lens of care and patient choice (2008). She problematises the concept of patient choice, discussing its positioning of health care in a rationalistic model based upon the tenets of consumerism and citizenship. The 'logic of choice' is contrasted with 'the logic of care', where both patients and practitioners, dually acknowledged as active negotiators of complex illnesses and bodies, collaboratively and continually attempt to use technology, science and other available means to develop liveable outcomes for patients (Mol, 2008).

Mol's discussion of interventions and technologies and their effects bears relevance to contemporary thinking in medical and social sciences. She demonstrates throughout her praxiographies and monographs that innovations are not obedient means to certain ends but are actors themselves, she goes further to propose a new ontology for thinking through medical interactions, that of enactment, multiplicity and ontological politics. I will further explore aspects of Mol's work in dialogue with my own findings in the coming chapters.

## 10.2 Paradox and non-coherence

In Vicky Singleton's book chapter: '*Stabilizing instabilities: The role of the laboratory in the United Kingdom cervical screening program*', she describes how local adjustments in a cervical screening program diverge from clinical protocols resulting in instabilities in the lab work. Conversely, instead of being a problem these instabilities help to maintain stability and produce the intended results (1998). In the same book, Charis M. Cussins describes other seemingly paradoxical findings. In her work, by exploring female patients in an infertility clinic, she questions whether 'forms of objectification per se...are antithetical to personhood.' (Cussins, 1998: p.167). She argues that medical technologies do not necessarily entail a loss of agency, challenging what she describes as longstanding ideas that technologies are objectifying and alienating, and potentially 'usurping selfhood' (Cussins, 2008: p.167) (a similar approach is evident in the work of Jeanette Pols, 2012). What she demonstrates is that women seeking impregnation objectify their infertility so as to pass through a number of medical spaces that may help the women to alter their identities as infertile women. The women, she argues, render themselves compatible with various instruments and materials so as to achieve potential transformation:

'She is locally and temporally reduced to a series of bodily functions and parts, working in a mechanistic way that forge a functional zone of compatibility with the means of medical intervention. The instruments, drugs, physician, gametes, and so on, all take on some form of her by standing in for the phases diagnosed as not working.' (Cussins,1998: p.192).

Cussins describes this work as 'ontological choreography' and concludes:

'woman's objectification, naturalization, and bureaucratization involve her active participation, and are managed by herself as crucially as by the practitioners, procedures and instruments. The trails of activity...wrought in the treatment setting are not only not incompatible with objectification, but they sometimes require periods of objectification.' (Cussins,1998: p.167).

Objectification is not necessarily an affront to the self and in some cases the women transform what it means to be objectified, medicalised women, with implications for conceptualisations of subjectivity.

The work summarised here could be considered as examples of practices where non-coherences and inconsistencies are managed, as working with multiplicities, subjectivities and possible non-coherences in a way that enables outcomes. In their paper '*Modes of Syncretism: notes on non-coherence*', John Law et al. explore the concept and ideal of coherence and the 'will to purity' (2013). They describe six styles of syncretism (non-coherence) that they see operating in the modern world. The authors take the term 'syncretism' from religious and anthropological studies where it is used to 'characterise more or less messy processes which combine, or perhaps particularly, secure, the temporary coexistence of practices and doctrines from a variety of dissimilar religious backgrounds.' (Law et al., 2013: p.176). Syncretism describes non-coherence made workable. In their paper, they ask how practices that do not cohere might be conceptualised and worked with if consistency and coherence were less idealised (Law et al., 2013). Of interest is how practices hold together when (as the authors suggest) all practices are syncretic (non-coherent). They describe *denial*, *domestication*, *separation*, *care*, *conflict* and *collapse* as syncretic styles. For example: *Separation* keeps non-coherent aspects apart through temporal, social and spatial divisions: 'different logics can co-exist so long as they do not collapse together in the same space and time' (Law et al., 2013: p.180). *Care*, another example, is described as a form of tinkering which is experimental and works on a bit by bit basis of small adaptations in the face of unfolding uncertainties and may allow for an imperfect and provisional holding together of effects in an ongoing process (For more on *tinkering* see Mol, Moser and Pols, 2013, for more on *care* see Mol, 2008 and Pols, 2010).

The authors do not describe this list of approaches to syncretism as exhaustive, complete or mutually exclusive. The different modes may depend upon each other and still represents a reduction of the described phenomena. This is what Hastrup would describe as an inherent process of knowledge claims, where reduction and selection are required to render the complexity in clear (Hastrup, 2004). Law et al. resist providing a conclusive response on



how non-coherence is managed in an aim to avoid yet another attempt at the ‘will to purity’. What they suggest is that:

‘the lesson we need to draw is that location, together with purpose or concern, unavoidably frames what will count as a good mode of syncretism...there is no place outside of time, space, place, and concern, where what is good or bad can be weighted up in an overall way’ (Law et al., 2013: p.182).

What is of interest in the work described in this section is the idea of ‘holding together’ in the face of complexity, multiplicity and non-coherence; how particular practices enable outcomes by managing potential paradox and multiplicity. The authors describe what the work may be in rendering non-coherence workable. This work also demonstrates how outcomes may come to be in unexpected and seemingly heterodox ways.

Each of the findings chapters below will include a discussion of literature relevant to the theoretical frame used to inform the analysis and construction of findings. The approaches used fall within the realms of science and technology studies, philosophy of science and anthropology and call upon the central themes introduced above.

### **10.3 Data Sources**

The two findings chapters in Part 3 call on different data sources. Chapter 11 considers the experience of patients testing HIV-positive in RHIVA through rapid testing specifically. The findings call on five in-depth interviews which are transformed into patient case studies. The methods used here are in-depth interviews and thematic analysis (See Chapter 4). Chapter 12 considers a synthesis of findings from the provider and patient level sub-studies to provide comment on the pragmatic trial method. I will now outline the data sources informing Chapters 11 and 12.

#### *Data sources for Chapter 11*

Throughout the trial period, 11 patients (of 4978 tested) were diagnosed HIV-positive in the definitive test with the initial test being the rapid HIV test (Leber et al., 2015). These rapid

tests were delivered as a part of the RHIVA2 trial. Patients diagnosed in this way, who received their HIV care at the local hospital, were invited for interview. The department of sexual health's research nurse, who was a member of the RHIVA2 trial team, was the first to approach patients about participating. It was only after a first occasion of consent, obtained by her, that I was introduced to potential participants. In all cases but one this was on the day of the interview, in the booked consultation room. On one occasion I undertook the coordination of the interview with the patient via email, after he had provided consent to the research nurse. Prior to beginning interviews I reintroduced the patient information sheet and consent form, discussing any questions before re-obtaining written consent and beginning the research. When possible, the interview took place when a patient was attending the clinic for a medical consultation, but in other cases the patient attended the clinic solely for the purpose of the interview. Participants were provided with a £20 voucher for their participation to cover travel expenses and the time given to participate. The amount was determined in consultation with the research nurse, who cited this amount as standard for this form of participation. Interviews with patients lasted approximately one hour and 15 minutes including the time allocated for introductions and consenting.

Six interviews took place with five participants, from a possible 11 who were eligible to participate. One patient, as a result of a mix up with recruitment at the local hospital, was interviewed twice. It is unclear as to whether all eligible patients were invited to participate and at least one patient opted to receive their care at a different hospital and so was not invited for an interview.

The small number of 11 patients diagnosed through rapid testing limited the potential sample of participants to be invited for interview. The research nurses reported some participants to be so fearful of social stigma and resistant to diagnosis that they did not want to participate in any HIV related activities beyond the biomedical tasks of diagnosis and treatment. The sample presented here, five patient cases, is not claimed to be representative or to have reached any form of data saturation. The value of small N studies is discussed in Chapter 4.

**Table 13.** Participant characteristics for patient-level study

<b>Sex</b>	<b>Age Range</b>	<b>Ethnicity</b>
Female	25-35	Black African
Male	35-45	Latin American
Male	25-35	Mixed white / Asian
Female	45-55	Black Caribbean
Male	45-55	White British

Interviews were in-depth and open ended. A topic guide was developed, identifying the following themes:

The experience of diagnosis:

- the GP setting
- the use of the rapid test
- the placement of the testing within the New Patient Health Check

Post diagnosis care:

- Pathways post diagnosis – How was your experience of entering services?
- Actual locations of receiving care
- Preferences for receipt of care
- Specialists vs. GP

Relationships with providers:

- Relationship with GP who diagnosed the patient
- Perceptions of the GP surgery
- Specialist vs. GP care
- Concerns

Transfer of specialist services into General Practice:

- Preference of health care locations
- Concerns about having HIV care in primary care settings

I introduced a number of questions as prompts if required but largely followed the lead of the patient in discussing their diagnostic experience.

A broader discussion of the patient case study features is described within the chapter. Briefly, interview transcripts were analysed thematically. Transcripts were uploaded onto NVIVO and coded twice. The first phase identified emerging themes. Following this, a coding frame was developed and applied to the transcripts. The second phase coded along the determined frame. The second coding frame contained the following themes:

- individual characteristics
- the experience of testing
- biosocial factors
- contrast to the imagined patient
- normalisation versus exceptionalism
- positive versus negative feelings and experiences.

#### *Data sources for Chapter 12*

Chapter 12, related to the pragmatic trial, calls upon data from the various sub-studies and the findings of the RHIVA2 trial. These include the interviews with nurses and health care assistants providing rapid HIV testing in intervention practices as well as interviews with patients testing HIV-positive as a part of the RHIVA2 trial with the first test being a rapid HIV test. My ethnographic attention to, and experience of, the pragmatic clinical trial also informs and in some ways provides the impetus for this chapter. Trial documents such as the trial protocol and training slide deck are used to articulate aspects key to the findings presented here. The results of the RHIVA2 also form a part of the data sources for this chapter. A broader and more detailed description of the methods and data sources used can be found in Chapter 4 (methods), as well as the previous 4 findings chapters. A further discussion of the approach to the findings, and how they emerged and were analysed is situated within Chapter 12.



## **Chapter 11: PRODUCING DIFFERENCE IN RHIVA2: HIV-POSITIVE PATIENT EXPERIENCES OF RAPID HIV TESTING**

### **11.1 Introduction**

‘The HIV test locates a spectrum of diseases waiting to happen, but not a disease itself. Partly because of this diagnostic ambiguity, the use of the test to assign meaning has engendered contentious social, political, moral and medical debate. When should it be used? On whom? What does the test really tell us? It has become clear that the social and political turmoil surrounding AIDS (the context) shapes the meaning of any HIV test. For some observers, the HIV test appropriately identifies a ‘sick’ and dangerous individual. For others the test itself has become dangerous, a vehicle for labeling, perpetuating social discrimination... Depending on its user, its interpreters, and the context, such a technology can have both oppressive and liberating effects.’ (Wailoo, 1997: p.2).

In Part 1, I demonstrated how the recommendation of considering HIV testing for new registrants in general practice was justified and enabled and the key discourses informing the policy. In Part 2, I explored the implementation and evaluation of the policy at the organisational level, outlining the factors inhibiting and facilitating the delivery of testing through the diffusion of innovations in health care organisations model by Greenhalgh et al (Greenhalgh et al., 2004). I now turn to the patient experience of rapid HIV testing as part of the RHIVA2 trial.

I begin by describing how the RHIVA2 trial team conceptualised the patient and their movement through the trial. I call this conceptualisation the ‘imagined’ patient. I then present the theoretical frame and the findings from the patient interviews before describing how the findings contribute to my understanding of Story 1: the ‘normalisation’ of HIV and the role of screening technologies in this process and Story 2: the logic of the pragmatic trial.

#### *RHIVA2 as a ‘difference machine’*

‘They are like spider webs, something will be caught in them, but one does not know exactly what it will be nor when it will come. They are devices for the creation of unprecedented events. Jacob has uniquely spoken in this respect of ‘machines for

making the future' (machines a fabriquer de l'avenir'), and thus of difference machines.' (Rheinberger, 2015: p.169)

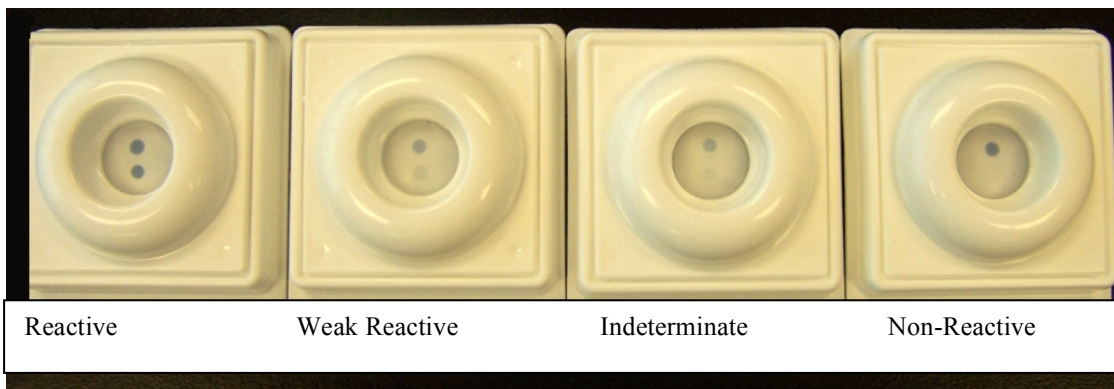
Broadly the RHIVA2 trial aimed to detect and demonstrate difference: A difference in the body represented by HIV and a difference between intervention and control arms in the trial. Hans-Jörg Rheinberger, a German historian and philosopher of experimentation in the life sciences, describes experiments as 'difference machines' (Rheinberger, 2015: p.168), as machines that attempt to make difference visible. Screening programmes aim to detect differences between members of the general population, which enables surveillance and medicalisation. The rapid HIV test works to make HIV intelligible, to make a particularity of the body visible and observed as a difference in need of care. The pragmatic trial aims to detect a difference between the intervention and control arms of the trial, this aggregated difference is then meant to be applied more generally. In a sense, RHIVA2 is all about determining difference.

In RHIVA2, this process begins with a patient attending medical services and agreeing to an HIV test. Patients are the key in this production of difference, determined by the answers to these questions: '*can we detect a difference (HIV) in the body of this patient?*' The answer is produced by the rapid test. Another question is '*is there enough difference in the bodies of these patients to help determine if we should look for difference in this way?*' The answer to this question is determined by aggregating the difference (HIV) between patients to demonstrate a difference between trial arms (trial outcomes: proportion of HIV and mean CD4 cell count). In this chapter I explore the patient role in producing these important differences: being tested for HIV and therefore constructing the trial results.

**Figure 9.** Determining differences in RHIVA2

**A difference in the patient body:**

The rapid HIV test aimed to detect a difference in the body of patients, through the detection of HIV antibodies. This image below was taken from the RHIVA2 GP training slide deck and was a tool to help clinicians learn how to detect HIV in patient bodies, made intelligible by the rapid test.



**A difference in trial arms**

The trial aimed to detect a difference between intervention and control arms of the trial, demonstrated through the rate of newly diagnosed patients and CD4 cell count. This text was taken from the trial protocol: Effectiveness of HIV screening in Primary Care: Study Protocol V 5.1, dated 02 August 2012

*‘The primary objective is to demonstrate that rapid HIV testing offered in the new patient health check or at first consultation, when combined with an educational package for health care professionals, reduces the proportion of newly diagnosed patients who present with advanced HIV infection from 30% to 10%. An advanced HIV infection is defined as CD4 count lower than 200 cells per cubic millimetre of blood. This is estimated from the mean CD4 count, using the Normal distribution.’* (Leber et al., Effectiveness of HIV screening in Primary Care: Study Protocol V 5.1 2012:8)

*‘The secondary objectives are to demonstrate (1) an increase in proportion of new HIV cases that qualify for the start of antiretroviral therapy, defined as a CD4 count less than 350 cells per cubic millimeter of blood (this will also be estimated from the mean CD4 count) (2) an increase in proportion of patients newly diagnosed in general practice (3) an increase in the rate of standard HIV tests performed opportunistically (4) a reduction in proportion of HIV cases with a high risk of progression to AIDS, defined as a viral load of higher than 200,000 copies per million peripheral mononuclear cells and (5) a reduction in financial and economic costs incurred to the PCT.’* (Leber et al., Effectiveness of HIV screening in Primary Care: Study Protocol V 5.1 2012:8)



## *The 'Imagined patient'*

In designing the RHIVA2 trial, we imagined and re-imagined the trial patient: what their pathway through services would be, what their CD4 counts and viral loads might represent if they tested positive, how they would feel about the rapid nature of the test, amongst other things. Before the first test was performed, a long anticipated patient was embedded in trial documents, training slide decks and ethical approvals.

In determining the eligibility criteria, we delineated who could form a part of the trial.

**Figure 10.** RHIVA2 Inclusion criteria slide from GP training slide deck.

**Who can I test?**

**Do Test:**

- 16 years and Up
- Test discussion in English or with a suitable translator.
- The patient agrees to the HIV Rapid Test

**Do NOT Test:**

- Known HIV positives
- Patients under 16 years - There is no upper age limit
- Those unable to engage in a suitable conversation about the test

Prior to undergoing the rapid HIV test the trial patient was to:

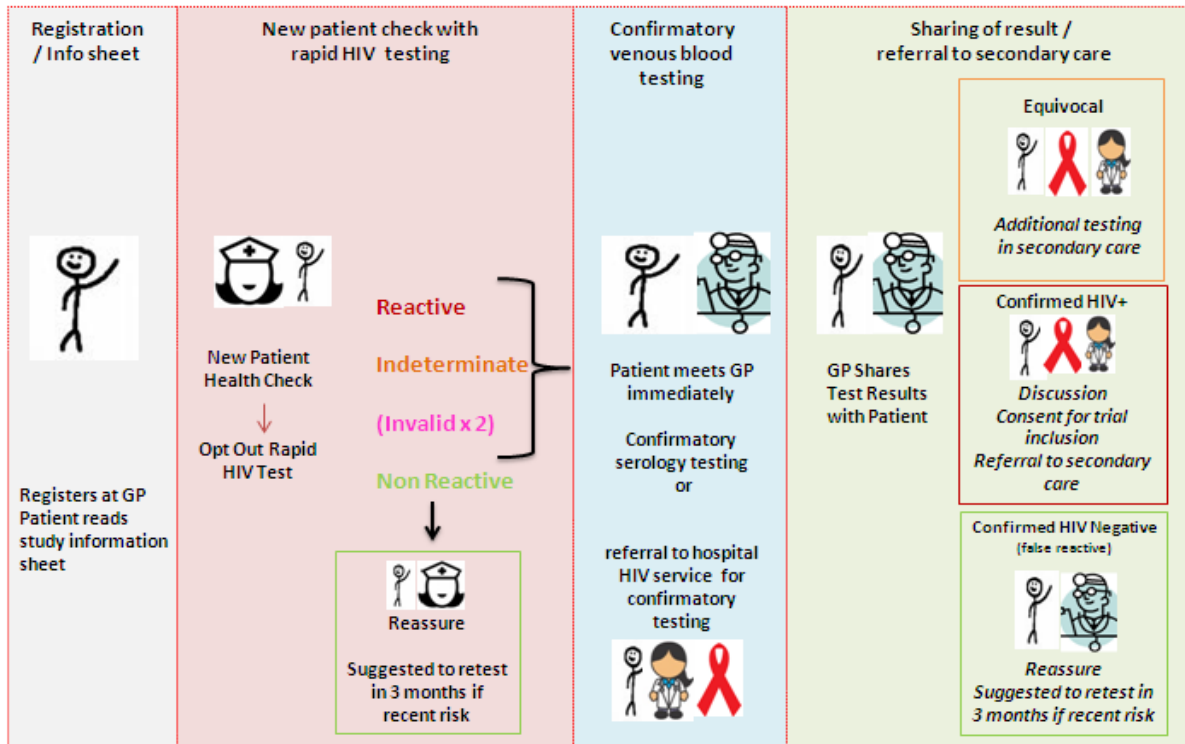
- Register with their general practice as a new patient.
- Receive and read a patient information sheet outlining the trial and notifying them that they would be offered a rapid HIV test.
- Attend a new patient health check (ideally within six months of registering so as to meet our data cut off for a new patient).
- Provide consent to undergo a rapid HIV test.

At the new patient health check, if offered, the patient would agree to the rapid test and have their finger pricked and their blood tested for HIV antibodies. Here a number of other assumptions are at work:

- The patient will be comfortable enough to notify the clinician if they are HIV-positive, despite it likely being their first visit to the practice for a ten-minute consultation with a health care assistant or nurse (not the GP).
- It will be clear when a patient is able to engage in a conversation and provide informed consent to undergo testing.
- The test requires sufficient blood sample (50µl). The patient needs to produce sufficient sample for the test to work.
- The test kits will be in date and properly stored as well as correctly operated by the clinician.


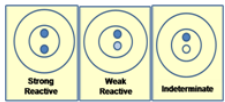
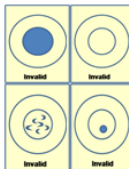
Our planning prioritised those receiving reactive results, as this required more extensive coordination. The two dots represented on the test membrane (See Figure 9.) would trigger a set of algorithms that transport individuals, body fluids and data to a number of locations to be met by various actors with key roles in the diagnostic journey of the patient and the success of RHIVA2. Figure 10 demonstrates an algorithm I developed in my role as RHIVA2 research assistant.

Figure 11. The RHIVA2 ‘imagined’ patient algorithm



Ideally, a patient would receive a clearly visible reactive result on the rapid HIV test membrane if their blood contained HIV antibodies. The nurse or health care assistant would then immediately access the GP who could explain the result to the patient and perform a confirmatory serology test. We developed phrases for health care assistants and nurses to assist them in enacting the algorithm and a desktop aid was provided to those offering rapid HIV testing as a part of RHIVA2.

Figure 12. RHIVA2 algorithm desktop aid

RHIVA 2 Rapid HIV Testing Trial – Interpreting and Acting on Results			
<p><b>Non – Reactive</b></p>  <p>“We did not find HIV today. If you have had any risk in the last 3 months you need to retest in 1 and 3 months time. Recent risk means sex without condoms, unsterile procedures or infected blood transfusions abroad, or sharing needles.”</p>	<p><b>Reactive or Indeterminate Result<sup>+</sup></b></p>  <p>“While we are awaiting the result of your HIV test would you mind taking a seat in the waiting room. A GP or nurse will see you shortly.”</p>	<p><b>Invalid x2</b></p>  <p>You need to have x2 invalid to classify the patient's results as invalid including in EMIS.</p>	<p><b>Actions:</b> Enter the result in EMIS. Contact GP. Take blood for confirmatory testing or refer to Homerton Hospital. Set up time to share result with patient. “Your rapid test is reactive. This means there is a high chance you have HIV. I will take some blood from your arm. We will then test this to get a confirmed HIV result, this result should be available .....”</p> <p><b>Actions:</b> If x2 Invalid enter the result in EMIS. Refer to GP to take venous blood. “Your rapid test result has been x2 Invalid. This means that there may be some problem with the test device. To make sure you are not infected, I am going to take some blood from your arm.”</p>

In the case of a reactive result, the algorithm assumed that:

- The patient’s HIV status is unknown prior to the rapid test.
- The patient will agree to the serology test.
- The patient will await the GP and remain located in the consultation room.
- The patient will accept the provisional result of the rapid test while awaiting confirmatory HIV testing.
- A GP would be available to speak to the patient.
- The patient will not participate in any ‘risky behaviour’ or defect from health care services while awaiting the confirmatory result.

The ‘imagined’ patient behaves in a rational, linear way, adherent to the suggestions of the medical setting and willing to participate in research. Some authors have critiqued the ‘normal science’ of trials and such conceptualisations of the patient. In their paper: ‘*An epidemic of orthodoxy? Design and methodology in the evaluation of the effectiveness of HIV health promotion*’, Susan Kippax and Paul Van de Ven critique the use of experimental methods, particularly the randomised controlled trial, in evaluating HIV interventions. They suggest that this form of investigation assumes research participants as ‘asocial individuals who occupy non discursive space in ahistorical time’ (Kippax and Van de Ven, 1998: p.371). Calling on an Australian health promotion strategy as an example, they conclude that the posited relationship between the variables measured, the health promotion materials, and the behaviours is over-simplified and that drawing associations would be inappropriate. They challenge the ‘orthodoxy’ of RCTs and describe a fundamental flaw in the trial logic, as even if performed ‘correctly’, they argue, the results would remain problematic.

‘people are social beings and as such they cannot be positioned as individual or atomized bodies as they can be in the clinical trial paradigm in which drugs are evaluated. Their lives are geographically and historically positioned; and they belong to groups according to age, ethnicity, sexuality, life circumstances, neighbourhood, employment and so on. In short they are socially and historically located.’ (Kippax and Van de Ven, 1998: p.376).

Understanding the conceptualisation and expectations of patients in RHIVA2 is important to allow for the contrast against the actual patients encountered to become clear. I will now outline my theoretical frame for this chapter before moving on to describe the patient cases.

## **11. 2 Theoretical Frame**

‘diversity will remain a feature of any complex practice, medical practice included. Instead of countering it, it would therefore be better to find more creative ways to handle it’ (Mol and Berg, 1998: p.7).

The body and subjectivity have been widely theorised in relation to health and illness. Important theoretical perspectives have included medicalisation, phenomenology, affect, enactment and performance, amongst others (See Lupton, 2012; Blackman, 2008; Mol, 2002; Pols, 2010). While this chapter discusses patient experiences of rapid HIV testing as part of the RHIVA2 trial, the subject of study is less the phenomenological, medicalised and sentient body, but what patient experiences of rapid HIV testing tell us about Story 1: HIV screening approaches as implementing a ‘normalised’ HIV and Story 2: RHIVA2 as an experimental design aiming to account for context using an RCT method. I pay attention to the specificities of HIV infection, particularly the normalisation of HIV and the enabling of the testing practices explored here and how this informed patient reactions to the trial algorithms and the intervention. I also attend to the construction of trial participants by first outlining how the patient was imagined in the view of the trial before describing how the actual patients encountered this conceptualisation and produced the trial results. I will begin with a description theoretical frames before describing the aims of this chapter.

### *HIV normalisation, multiplicity and the specificity of disease*

The work of Annemarie Mol and her ontology of disease has been described elsewhere in the thesis (See Introduction to Part 3). Of importance here is the proposition of a multiple ontology of disease and how this can come into view by exploring medical practices enacted in different sites, in different ways and by various actors. As described in Chapter 7, a diversity of HIVs can be seen operating in the policy literature and I have described one of the two stories informing this thesis as RHIVA2 aiming to implement a ‘normalised’ HIV’, a HIV that is a chronic, treatable, potentially non-infectious, long-term condition better detected in the early stages. To reiterate, screening for HIV, can be seen as a ‘normalising technology’ (Philbin, 2014) or practice, and considered as part of the discursive push to ‘normalise’ HIV for which there is a nascent body of literature that both explores and challenges how this ‘normalisation’ is experienced by individuals with HIV (Persson, 2013; Newman, 2015; Mazanderani, 2015; Mattes, 2014; Philbin, 2014; Moyer and Hardon, 2014; McGrath et al., 2014; Flowers, 2013) (As discussed in the Introduction of Part1 and in Chapter 7). These authors explore the complexities of interacting with an infection that holds such a socially and symbolically charged history from a patient perspective with emphasis on the push towards ‘normalisation’. This work could be considered a form of ‘sociology of disease’, where emphasis is placed on the impacts of particular diseases on aspects of social life (Timmermans and Haas, 2008).

In their article *‘Toward a sociology of disease’*, Timmermans and Haas explore the recent history of the sociology of health and illness articulating areas for broadening sociological work on disease (Timmermans and Haas, 2008). They begin with the seminal work of Talcott Parsons, who conceptualised illness as a deviant form of behaviour that required medical professionals to legitimise illness and restore patients into functional citizens. Parsons delineated the roles of both patients and providers and highlighted the social factors involved in different stages of illness and cure. Many sociologists of medicine, according to Timmermans and Haas in their wide-ranging review, emphasised ‘experience, culture, and social structuring of illness while bracketing the biological bedrock of disease’ (Timmermans and Haas, 2008: p.660). This, they argue, has resulted in a rich writing of sociological experiences of illness and numerous broad sociological explorations of what it means to be

unwell, but, they argue, ‘the price paid for conceptual amalgamation is an important loss of specificity’ (Timmermans and Haas, 2008: p.664). Their review outlines four critiques and calls for a broadened and more biologically based sociology of disease. A sociology of disease, they argue, should take interest in disease specifics:

‘social scientists rarely make specific diseases central to their inquiries. Instead, sociologists tend to study health conditions at an abstract level of conceptual aggregation, or, alternatively, focus on the multiple ambiguities of disease diagnosis. In everyday life, however, most patients and health professionals deal with specific diseases (Rosenberg 2003).’ (Timmermans and Haas, 2008: p.662)

In calling for a more robust sociology of disease which does not ignore the specificity of particular diseases including their biological basis they provide three broad critiques. These include how social scientists: rarely make specific diseases central to their inquiries, rarely include clinical markers of disease in their analyses and tend to ignore the normative purpose of health interventions. They summarise by stating how:

‘these omissions reflect a social science studying medicine pragmatically as a site of social action, while ignoring what makes medicine medicine: its existential, ontological, and purposeful dimension of diminishing human and social suffering.’ (Timmermans and Haas, 2008: p.662).

This insight will be considered throughout the findings presented in this chapter.

### *Experimentation and subjectivity*

Vinciane Despret is a philosopher of science and a psychologist. Her work, exploring experiments and human-animal relationships, suggests alternative ways of thinking about science, objectivity and experimentation. One of her themes is ‘the subject’ and subjectivity in science (Despret, 2013; Latour, 2004). Of central importance to Despret is the space and the awareness for the subjects of research to ‘respond’ to the experimental probe, potentially with their own questions. She describes this in the quote below:

‘One of the ways to resist an apparatus is to lead the experimenter to transform his/her question into new ones that are appropriate questions to ask that specific individual. In other words, an apparatus that does not have a stake in docility is an apparatus that is designed to give the opportunity to the ‘subject’ of the experiment to show what are the most interesting question to address to him; what are the questions that make him or her most articulate.’ (Despret, 2004: p.124).

One way the experiments explored by Despret create their outcomes is through a process of what she calls 'attunement' (2004), where the researcher and the subject attune themselves (through reactions and responses) to each other and to the experimental probe. In *'The body we care for: figures of anthropo-zoo-genesis'*, Vinciane Despret describes experimentation and explores the example of Hans the horse. Here, a number of scientists were intrigued by the apparent ability of Hans the horse to solve mathematical problems and queried how this could be possible. What becomes apparent in Despret's analysis of events is that the horse became an experimental apparatus with the ability to affect the researchers as well as be affected by them. Affect is described by Clough as the:

"potential bodily [and] often autonomic responses" (2); different from emotion, which reflects in part the product of meaning-making processes, affect exceeds consciousness: it refers to pre-subjective agency, a force that delimits bodily boundaries, determining "bodily capacities to affect and be affected" (2). (Hoon, 2009: p.155)

The horse responded to the small unconscious body movements of the researchers and as a result knew when to stop or continue counting. The researchers unconsciously communicated with Hans the horse to help produce the result. Hans could read bodies, but he could also affect the bodies of the researchers without their knowledge. Together, in this process of what Despret calls 'attunement', the researcher and Hans could make articulations visible, the horse became 'a device that enabled humans to learn'. (Despret, 2004: p.126). What there was evidence of, in this case, was attunement versus counting, per se.

Similarly in describing the scientist Irene Pepperberg's work on language learning with a parrot named Alex, Despret develops insights on translation and misunderstanding in experimentation. Again Despret describes a process of attunement, which becomes the experimental apparatus. It is in this process of adjusting to reactions and responses and research subject participation and agency (conscious or otherwise) that the results can take hold. In the quote below she describes the importance of 'overlapping desires' between the experimenter and the subject:

'Alex talks because Pepperberg desires it and demands it of him, and because she was able to subordinate her desire to what makes sense for Alex in the matter of speaking. She was able to negotiate with Alex over what in speech could interest him. Alex talks because for diverse reasons his desire overlaps with that of Pepperberg. In other words, Alex doesn't talk in the name of a "we" of parrots successfully imposed by



scientists, but in the name of a “we” constituted by the assemblage of a parrot and human beings equipped with an apparatus aimed at making the parrot talk well.’ (Despret, 2008: p.127-128)

Despret describes a coming together of subjects, researchers and an experimental apparatus that adjusts to combine both the desires of the parrot and the researcher to produce particular, situated results. Following this, Despret determines that ‘generalisability is always possible, but it is constructed in another way: it is constructed bit by bit’ (Despret 2008: p.128). She goes on to further delineate her concept of attunement, referring back to the work of Pepperberg:

‘Meanings are constructed in a constant movement of attunement, which makes them emerge. This strategy which tunes up meanings, which gives them and adjusts them, is inscribed more broadly in Pepperberg’s work in an apparatus that redistributes control’ (Despret, 2008: p.125).

While Despret uses these concepts to further delineate findings on embodiment and affect quite specific to animal and human experiments, the broad conceptualisations she presents in regards to attunement, experimentation, subjects and generalisability are relevant to this thesis and can be used to explore how participants interacted with the experimental intervention and therefore constructed the trial results.

The work described above can be seen to pull together a number of broad themes relevant to what is presented here; the sociology of disease and diagnosis, relevant to Story 1, and theories of experimentation and attunement, relevant to Story 2. Some of what this theoretical frame describes is how what may seem paradoxical or non-coherent can be what produces particular outcomes. These outcomes are contextual and involve the specificities and subjectivities of diseases, individuals and materials to produce the results. How experiments, practices and interventions are situated is key, as is the space for emergence, be it of participant questions, the practices that render non-coherence workable or for the attendance to multiplicity. It follows that objectivity and subjectivity as understood in an evidence based medicine paradigm are destabilised and actor agency (conscious or otherwise) becomes not only apparent but often essential to achieving outcomes.

### 11.3 Introduction to the findings

In consideration with the literature outlined above, in this chapter I ask: how did the participants explored here make the intervention, and therefore the trial, meaningful to them? What was *good* for patients in RHIVA2? To follow Despret: What questions were patients asking of the intervention? This approach allows for insights into both the patient experience of the trial and rapid HIV testing but also into how the trial outcomes were produced, explicitly taking into account what was of interest to the patients. According to the logic of experimentation outlined by Despret, if there is space for the questions of the research participants to emerge and ‘attunement’ takes place, here is where the experiment has the opportunity to become meaningful for both the patient and the research, and for the results to take hold. How did this happen in RHIVA2? By exploring the role of the ‘normalisation’ of HIV in patient experiences, I attend to the specificities and temporalities of HIV infection locally, responding to the call by Timmermans and Haas for a sociology of disease concerned with disease specificity. By drawing out what was ‘the good’ for patients, I attend to the normative dimension of medicine as improving the lives of patients and make an applied contribution to the field of HIV testing and care.

The small sample of patients has allowed me to develop thick descriptions that explore various dimensions of patient experience in the trial. Each patient experience will be described in a similar way that describes key themes as they relate to the questions explored in this chapter. I will briefly describe each finding theme explored in the patient write ups before going on to introduce the patient findings.

*The patient/ the individual / the research participant/ the subject/ the service user*

Knowing how to describe the individuals’ diagnosed HIV-positive as a part of the RHIVA2 trial has not been straightforward. In the field of HIV much care and nuance is used in describing those living with and affected by the virus. I consider this approach a key aspect of the culture of the HIV community, where patient rights, respect and attention to identity and the power of words are much discussed and considered. I have chosen to provide fake names and to change patient details to ensure confidentiality and anonymity. Otherwise I largely refer to individuals as patients or participants to represent their dual status as both

patients of the NHS and participants in research. Under this heading I introduce the participant and describe how they encountered the RHIVA2 trial.

### *The test*

In this section I recount experiences of testing to provide empirical examples of how rapid HIV testing played out for patients in RHIVA2.

### *HIV as 'biosocial'*

Under this theme I describe some of the social and relational context for each participant. As HIV is an infection passed between particular human bodily fluids (blood, semen, vaginal and rectal secretions, breast milk) it is inherently social: it was acquired through someone in a bounded way. As a result, an HIV infection could be seen as an embodiment of particular social relations or acts. The social practices that transmit HIV are among the most intimate: having sex, being born to a mother living with HIV, sharing injection equipment or undergoing a medical procedure with infected blood products. A relationship with someone and likely a practice undertaken with them resulted in a new category of illness and likely a shift in identity and behaviour with profound long-term implications. What was apparent in the data was how an HIV diagnosis inspired a form of social investigation. Individuals immediately began to trace social interactions, sexual experiences and behaviours, as well as anticipate the reactions of loved ones. What was pertinent to participants was the transformation the diagnosis would have on social life and how it recast relationships and experiences. Those interviewed spoke more about their relationships, their sense of self and their futures post-diagnosis than about their biomedical indicators or general physical well-being. Social realities impacted participant's relationship to testing, as said by one participant:

‘What I think is missing from this survey is more emphasis on the relationships that the individual, the patient is within prior and post diagnosis. ...It's perhaps the biggest factor in whether you test and how you test.’ (Tom)

It follows that a section highlighting the ‘biosocial’ context of HIV for each patient forms an essential part of the findings.

### *The imagined and the actual patient*

In this section I describe how the patient encountered sits in contrast to the ‘imagined patient’, as described earlier in the chapter. It becomes apparent that many of the categories and algorithms assigned to the imagined patient and their journey through RHIVA2 sit in contrast to the experiences of the patients encountered. We find that patients are not necessarily newly registering, asymptomatic, HIV-negative or agree to testing for the purpose of diagnosis. Initially, one might consider these findings as demonstrating non-coherence, or that this presents problems to the trial findings, but what becomes apparent is that these instances that enact patient particularities and subjectivities are essential to constructing the trial results.

### *What was ‘the good’ here?*

Various social scientists suggest considering what is ‘good’, for who and where, versus trying to determine a singular ‘truth’ of particular interventions or experiences (Mol, 2002) (Law, 2011). Here, I follow Despret’s suggestions of considering the questions research participants pose to experimental research and explore what was meaningful for patients in the experimental interaction. I extend this to discuss what was ‘good’ for the patient testing HIV-positive through rapid testing in RHIVA2. What is ‘good’ for patients sometimes sits in contrast to the objectives and assumptions of the trial but also allows for the trial results to take hold.

## 11.4 Patient Cases

### *Joy*

Joy is a friendly African woman in her thirties. New to the UK, she was feeling generally unwell with fatigue and a sore throat. At the encouragement of her cousin, Joy registered with her local general practice. When Joy was offered an HIV test, she agreed. She had no reason to believe she had been at risk for HIV but was keen to figure out why she had been feeling so unwell, as a result she was agreeing to any tests that were suggested.

#### The test

When the rapid test was reactive Joy was shocked. She is unsure of how she may have contracted the virus but believes it may have been through a medical procedure performed in her home country a few years prior. Joy was a late diagnosis. She began treatment immediately and had a very low CD4 count (an indicator of the stage of infection).

#### *HIV as 'biosocial'*

Coming to terms with her status has been challenging and very few people are aware Joy is HIV-positive. The majority of her concerns relate to relationships, dating and the opportunity to have a family. She finds negotiating disclosure of her status very difficult when beginning new relationships and fears that her status will become known in her wider community if she tells the wrong person. She does not want to be gossiped about. As a recent migrant, Joy did not have a pre-existing network of friendship and support and she relies heavily on her cousin, who is aware of her status, to assist her with her financial and emotional needs.

#### *Joy and the 'imagined' patient*

Joy meets the inclusion criteria for the trial and aligns fairly closely to the imagined trial patient. However, she was symptomatic and seeking a diagnosis. As a late-diagnosis and

unaware of her infection, Joy is the type of patient whom population screening in primary care aims to locate and enter into specialist services. She didn't report any problems with the trial algorithms or her diagnostic experience.

*What was 'good' for Joy in RHIVA2?*

What is good for Joy in RHIVA2 is learning why she is feeling unwell, being treated kindly and supportively and learning that much has changed in HIV.

As Joy was unaware of her risk for HIV, the offer of an HIV test was perceived by Joy as part of a thorough health check up. Receiving and coming to terms with the result however has been a challenging process and not something she would describe as 'normal'. This may go some way towards explaining why Joy loves the HIV clinic. This is a space where she feels accepted and cared for. Socially marginalized in multiple ways and apparently isolated, attending the specialised HIV clinic appears as a positive event and activity in her life. She is keen to participate in research and was interviewed twice. Joy says she would be resistant to receiving care in general practice, because of the positive feelings she feels at the specialist clinic, in particular for her Doctor (*'I love him. He is a good man.'*).

Joy also described her relief at learning she would be able to become a mother while HIV-positive, without passing the infection onto her child. It became apparent that the HIV Joy thought she was being diagnosed with was different from the HIV understood to legitimate HIV screening. Unaware of the improvements in treatment and prevention that have reorganised the biomedical meaning of HIV infection, Joy believed she was being diagnosed with an HIV that was more lethal and limiting. The work of the specialist here could be seen as 'aligning' HIVs, the 'new', normalised HIV with the HIV understood by Joy, which may go some way toward explaining why Joy finds specialist services so comforting.

### **Casey**

'I've never got tested before, I'm that kind of person that won't go to the doctor unless I really have to go...I would never have found out. I'd still be clueless if I

didn't go to the GP and get tested there because I would never go to a health clinic to get tested, no. It's just the type of person I am.' (Casey)

Casey, a young gay man from the Americas, has been living in London for a few years. Following a difficult break up and a few sexual encounters he contracted HIV. He decided to register with his local general practice due to some skin irritation that didn't seem to be healing. He describes himself as '*not the kind of person who goes for tests*', and did not undergo regular sexual health screens. He was generally reluctant to go for medical checks of any kind.

### *The test*

'It was just lots of waiting around and I guess the anxiety came from being told you would find out a certain day and not finding out that day. If it was the case that they said to me we won't know for sure until we get the result three weeks from now, then that would've been easier to deal with and cope with than saying you'll know two days from now and oh shit, we'll let you know next week, and actually you have to go for another blood test to confirm it the next week and they can't really tell you if you have it or not a week from then, which is not very fun. I joked that I got told I was positive three times in a month!' (Casey)

Casey's experience of diagnosis was fraught with logistical problems which resulted in preventable emotional stress. First, he did not realise he may have contracted HIV. Professionally trained in science, he had considerable insights into the mechanisms of the rapid test. Casey claims to have known the result prior to the GP becoming available to share it with him and had to endure the nervousness of a nurse who told him it might be a 'false reactive' in what appeared to be an attempt to provide comfort. The GP he then spoke to was unsure of the algorithm for confirmatory testing. Casey was assured that he would receive his results within the next two days but did not; he was then contacted by the GP to indicate his results had been lost. In total it took him approximately two weeks to get a confirmed HIV diagnosis and furthermore, while having his blood taken at the local hospital there was a fire drill. Despite this, Casey expresses gratitude for the rapid test, indicating that his lack of health seeking behaviour would have meant his HIV infection would have gone undetected for some time.

### *HIV as 'biosocial'*

'The difficult part was telling my ex-boyfriend and making sure he got tested and figuring out if I gave it to him or if he gave it to me but it turns out he was ok so I must've gotten it after him, which made it even worse actually. I don't know if that makes any sense, it's worse for me to have gotten it from some random stranger because I was upset over breaking up with my ex-boyfriend and going through all the hell. Then at the back of my head, maybe he was lying to me, I don't really know. That was the hardest part. The moment he told me he was fine was the hardest day probably of my experience so far in my young [X] years of age' (Casey)

Casey is still coming to terms with his diagnosis and expressed a range of coping mechanisms throughout the interview. He feels lucky to have a work place that is supportive of his status as well as friends who support him and have taken it upon themselves to learn more about HIV and attend his appointments with him if he wishes. The majority of Casey's distress surrounds the end of a relationship just prior to him contracting HIV. In the midst of heartbreak, Casey found having to tell his former partner about his status extremely difficult. He also describes an urge to tell his family, so as to be open with them about his life, but also feels some reluctance to do so fearing it might cause them pain.

### *Casey and the 'imagined' patient*

Broadly, Casey is close to the trial's 'imagined patient': He was a non health-seeking individual who as a man having sex with men in London was at high risk of HIV. He was unaware of his status and likely would have remained undiagnosed for some time. As a result of the trial he was diagnosed early and transitioned effectively into secondary care. However, Casey's transition through the algorithms set out in RHIVA2 was far from seamless and a number of issues presented themselves in his journey through the research and medical algorithms. Consequently, Casey's experience of 'rapid' testing was not so rapid. While the initial rapid test did provide a quick result, the nurse initially struggled to present this information to him effectively and his confirmatory testing results were lost in the process. Overall, Casey's diagnosis took much longer than if he had received testing in the traditional sense of attending a GUM clinic or undergoing a venous blood test at the GP, however, as indicated by Casey, he never would have done this.



*What's 'good' for Casey in RHIVA2?*

It's quite funny coming in here (the hospital) because I sit down and everyone has to grab a ticket and fill out a form and I'm just like, I don't need to do that. I'm special...at the GP, I wouldn't be doing that.' (Casey)

For Casey, what is good is feeling '*special*' but also feeling like HIV is less of '*a big deal*'. Casey expresses many of the tensions in the normalisation logic. He enjoys the specialised care and attention he receives in the specialist setting as well as the way the consultants treat HIV as if it is not such a 'big deal' while still attending to the specificities of the infection.

'Because it isn't a big deal anymore, so it makes it less of a big deal if you are just going to the GP. You only really need to see a specialist if it's something that's untreatable or you're going to die in ten years or need constant care. But I don't need constant care. I need to be able to get myself blood tested every six months or so. But then from someone who's just been diagnosed, not more than a year ago, I'm just like, I think I'm a bit of a special case, a bit more special than other people. It's also just the perception of it, not just from the clinical point but from the general world. People still think it's a bit like, you might die soon. I still think I am going to die soon but we'll see! For the future, having it slowly transition to the GP level makes a lot more sense and the more people learn about it, the more people realize it's not a big deal and you're not going to get infected by sharing the same toothpaste or something, the better.' (Casey)

What was not good for Casey was waiting around and being a liminal position regarding his diagnosis. Feeling like he had more knowledge than the providers at the general practice about HIV and enduring a nurse telling him 'it might be a false reactive' were also unhelpful. He understands why HIV should be 'normalised' but does not feel the way HIV is perceived publicly or experienced by somebody recently diagnosed represents normalcy. As a result what is good for Casey are services that make him feel like HIV is normal while still acknowledging how impactful the diagnosis is.

## *Angelique*

‘The partner that I had at the time, he passed HIV onto me and then I don’t know if he had himself checked out because he was losing a lot of weight too, but I didn’t think of anything, but it is surprising he just cut me off with no explanation, nothing, he just cut me off. He just stopped seeing me completely and then a few months down the line a friend of mine told me he was in intensive care with [an indicator condition]. He died and I’m still here.’ (Angelique)

Angelique is an English Afro - Caribbean woman in her fifties; she is a mother and is currently in a loving relationship. She suffers from a number of health problems. Angelique became very concerned when she began to lose weight, she felt something was not right.

### *The test*

Angelique went to the GP and pushed her Doctor to uncover what might be causing her weight loss. After a few visits and undergoing tests for other conditions her GP thought she should be offered an HIV test after researching her symptoms online. Instead of offering her a blood test, the GP booked her an appointment with the practice nurse for a rapid HIV test at a separate visit. Angelique returned to the practice for this appointment and the rapid test was reactive. The GP was not immediately available to meet with her but Angelique decided to wait at the surgery until close in order to discuss her result with her doctor. Angelique demonstrated significant tenacity in obtaining her diagnosis and getting the care she needed. She is now taking medications regularly and feels some sense of satisfaction for being so proactive in her diagnosis.

### *HIV as ‘biosocial’*

Angelique’s persistence in achieving a diagnosis may hold particular emphasis as her previous partner suddenly stopped speaking to her, was admitted to hospital and then died. Realising that this was likely HIV related, she feels that by insisting on her investigating her symptoms may have avoided a similar fate. Despite this gratitude, she finds the number of

medications she needs to take a burden and suffers from depression which she relates to her numerous health conditions. In general, she feels she is living fairly well with HIV and despite her exhaustion regarding medications she is glad the '*drugs are doing their job*'. Angelique acknowledges the important role her family members and her new partner whom she thought '*would run a mile, but didn't because he said he was in love with me*' play in helping her manage her various conditions and medications and in keeping her feeling '*ok*'.

The regular medical appointments, medications and overall maintenance of her health is troubling for Angelique. HIV adds another level of complexity to her existing health concerns and contributes to her depression. It appears that Angelique's partner may have hidden his HIV diagnosis from her. This may be representative of the stigma attached to HIV. As a result, Angelique sought medical services and persisted in gaining an explanation.

#### *Angelique and the 'imagined' patient*

Angelique was not a new patient. She demonstrated significant tenacity in reaching the HIV test. Her doctor improvised the use of the rapid HIV test to help her receive a diagnosis. However, this was curious, as instead of immediately taking blood, she was booked a separate appointment and did not have immediate access to a doctor when receiving her diagnosis. Angelique had time to mentally prepare for the test. Despite this and having had her doctor already raise the possibility of HIV with her, she wanted to speak to him immediately after the test. She demonstrated resolve once again in waiting for the practice to close so that she could have a few minutes to speak to her GP. Angelique's experience disrupts the assumptions of the trial as she was symptomatic and seeking diagnosis, not a new registrant; was a candidate for venous blood testing and could not immediately access an appropriate professional to discuss her result. Despite this she is read as a new patient with a successful transition through the trial and the medical system in the trial logic.

### *What was 'good' for Angelique in RHIVA2?*

What was good for Angelique was getting answers to questions about her ill health and the behaviour of her partner. What has also been good for Angelique are specialist services who were able to provide information and support to her family members so that they may better support her and her multi-morbidities. What is not good for Angelique is managing the biomedical regimens of visits and pills. While Angelique did not complain about the multiple visits and various health personnel involved in her diagnosis and is generally grateful for her diagnosis and care, the tenacity demonstrated by Angelique reflects a personal characteristic that may be absent in other patients symptomatic of HIV and seeking answers.

### *Tom*

'I had been using recreational drugs for two years, and they greatly influenced the risk taking behaviour. Everybody knows it but it's a huge difference. I'd been safe for 18 years. I'm not saying I regret it, because the awful thing about being safe all your life is you see sex as something dangerous and scary, and in some ways it's not worth living like that.' (Tom)

Tom is a Londoner in his fifties. A gay man, he describes himself as a spiritual person who loves his family, nature and animals and who is very interested in '*truly becoming the person that I am*'. He also describes himself as '*growing up with AIDS*'. Prior to becoming HIV-positive, he felt that HIV was a part of his identity due to its prevalence in the gay community, to having lost many friends to AIDS, and to participating in large scale awareness raising campaigns ('*it's inescapable for a gay man of a certain generation*').

### *The test*

'It was a Friday afternoon. I was in a state. I wasn't expecting it. I didn't go to the clinic for an HIV test. I had no psychological preparation. I had that split second where I decided okay I'll do it. And so I started feeling 20 years of fear, and I think we said that we would do (the test) again and we did it again and it was the same and I said 'can I see a doctor', and she phoned up the head of practice, and I heard him on

the other end. He was supposed to be on call, and he said he wasn't going to see anyone, and I was very upset with this.' (Tom)

Tom had recently moved general practices quite reluctantly. He had become close with a clinician at his previous surgery and it was felt inappropriate by his former GP for him to continue there. Tom regularly attended GUM clinics for sexual health screening including HIV testing. He has recently been enjoying 'chem sex', where individuals take a number of pleasure enhancing drugs and engage in sex with multiple partners, often over a period of days (Bourne et al., 2015). As a result, and despite doing his best at practicing 'safe sex' by beginning with condom use, he realised he may be at risk of infection. Tom attended his new surgery for a new patient check on a Friday afternoon and was surprised at how unprepared the practice was in dealing with his reactive result. He agreed to a test when it was offered despite usually opting for HIV testing at a specialist centre. Tom describes himself as '*urban*' and prefers the hospital to the '*mom and pop units*' of general practice. Upon learning of his reactive result, the nurse told him it may be a false reactive (also seen with Casey). She then went to contact the GP to share the result, only to find that there was not a GP present in the surgery. Additionally, the last blood tests had been picked up for the weekend and so Tom was referred to the hospital for confirmatory testing. As then hospital was also closed, Tom spent the weekend without a confirmatory test or any professional support for his reactive HIV test result.

#### *HIV as 'biosocial'*

Tom feels privileged that he was able to share his result immediately with his partner and close friends. He accessed a circle of support within his community and has taken his diagnosis as an opportunity for personal and spiritual growth. He is keen to participate in research and help improve services. Tom feels the impact of an HIV diagnosis on identity and relationships needs to be further considered in biomedical research as the diagnostic experience can open up psychological wounds and provoke intense self-inquiry.

### *Tom and the 'imagined patient'*

Tom's knowledge about HIV and sexual health service best practice impacted his opinion of the way HIV testing was offered and dealt with in RHIVA2. The 'expert' knowledge Tom had regarding HIV may be a hallmark of its historical exceptionalism: involvement in a disease-related social movement, heavy promotion of safe sex practices to his community and being well versed in patient rights and best practices in HIV care. Tom was much more educated in these domains than the 'imagined' patient.

### *What is 'good' for Tom in RHIVA2?*

'What I am trying to say is there wasn't a sort of consultation. It was rather business like, and added into this mix was something which for them was routine but for me was not.' (Tom)

'My only thing is, it's not having it sprung on me. It's being dropped at the end of it... you've got to anticipate what you would do with a positive result, a first positive result, and this primary care trust had not gone that far on its thinking, certainly not on this particular afternoon.' (Tom)

For Tom, the trial algorithms did not kick in as intended. He strongly feels that rapid HIV testing in general practice without greater access to psychological services is inappropriate. As a result, Tom found testing as done in RHIVA2 acceptable in theory but unacceptable in how it was practised. He did not feel the test was optional. The specialist knowledge (GP, HIV specialist or counsellor) he felt he needed was not accessible. What is good for Tom is specialist services, which he feels better attend to his identity as a gay man with expert knowledge of HIV. What would have been better for Tom are services that are prepared to deal with psychological impact of a positive HIV result. What also appeared to be good for Tom was personalised care and feeling linked into the wider HIV community, which specialist services appeared important in providing.

### *Oscar*

'Despite me knowing for 10 years, I had already been a carrier for 10 years without any member of my family knowing about it. So ten years and no one in my family

knowing, for me, so much time. This step was difficult for me. To make this step, to continue doing this bit for my family, so much harder knowing that they would go through pain because of me.’ (Oscar)

Oscar is in his forties and from the Americas. He is a father and a gay man who spent many years living in a European country prior to migrating to the UK to be closer to family. Oscar had been aware of his HIV status for over a decade and was successfully receiving treatment for many years. When moving to the UK he made a conscious decision, in collaboration with his specialist doctor in the European country, to discontinue his HIV medication until he could effectively transition into the health service here in the UK. He feared that disclosing his status would bar him entry to the country or result in deportation, compromising his prospects of building a new life in London. Oscar decided to risk destabilising his HIV infection in order to try and make a smoother transition into UK life.

### *The test*

When Oscar registered with his local general practice he was pleasantly surprised to be offered a rapid HIV test. Oscar does not speak English and was accompanied by a family member. The health care assistant offered him the HIV test, using the family member as interpreter. Oscar’s HIV-positive status was not known to his extended family and friends network. He saw the rapid HIV test as a way to manage his transition into the UK health system that did not require him to actively disclose his status. Additionally, Oscar’s need for an interpreter to register with the GP meant that a family member was present during his test. This unexpected occurrence provided Oscar with the opportunity to share his status with his family. Oscar is now feeling healthy and comfortable with his open status. However, throughout his transition into the UK and into the health service Oscar was admitted to hospital with an infection, which both his specialist and the neurologist speculate is related to his HIV infection and his interruption in treatment. This caused Oscar temporary disability.

### *HIV as ‘biosocial’*

What is perhaps of greatest significance to Oscar is overcoming his guilt of fathering a child while being HIV-positive. He felt his family might judge him for this despite the child being

HIV-negative. Now that his status is ‘out’ he has been able to put this guilt aside and successfully continue his happy family life in the UK. Oscar recovered from his infection and is living well with HIV. He feels that HIV services in the UK are helpful and supportive. He values free HIV care as he paid for private care in his former country, partially due to this immigration status.

### *Oscar and the ‘imagined’ patient*

‘Yes, it was very hard. It was a bit of a shock because I was already scared that the GP wasn’t going to accept me, and plus, on the other side, I was scared to tell my family, then I had to do both at the same time.’ (Oscar)

If Oscar was experiencing another illness he may not have feared entry into the UK or put off disclosing to his family. He may not have undertaken a complex coordination of medications and strategic action with his former specialist to conceal his illness to achieve other objectives. HIV as a socially stigmatised infection shaped Oscar’s interaction with his family, the state, the health care service, his medications and his own body. Additionally, Oscar did not fit the inclusion criteria for the trial (HIV-positive/ ‘suitable’ translation). Oscar repurposed the rapid HIV test for his own means. He used testing as a way to manage other aspects of his life, his immigration and his relationships. The RHIVA2 trial assumed that rapid testing would detect patients unaware of their infections. Oscar’s experience challenges the linear process assumed by the trial and the compliant way that patients would experience testing. Oscar also raises important questions about how the RHIVA2 results were achieved.

### *What is ‘good’ for Oscar?*

What was good for Oscar is finding a way to resolve his fears around disclosure and deportation; he was relieved to find that the UK was more ‘HIV friendly’ than he anticipated. What is also good for Oscar is being able to restart treatment with the help of specialists. Oscar also describes being able to share his status with his family as enabling him to get past his guilt for having a child while being HIV-positive. Oscar was able to achieve these aims due to there being enough space in the intervention to allow his questions and objectives to be resolved.

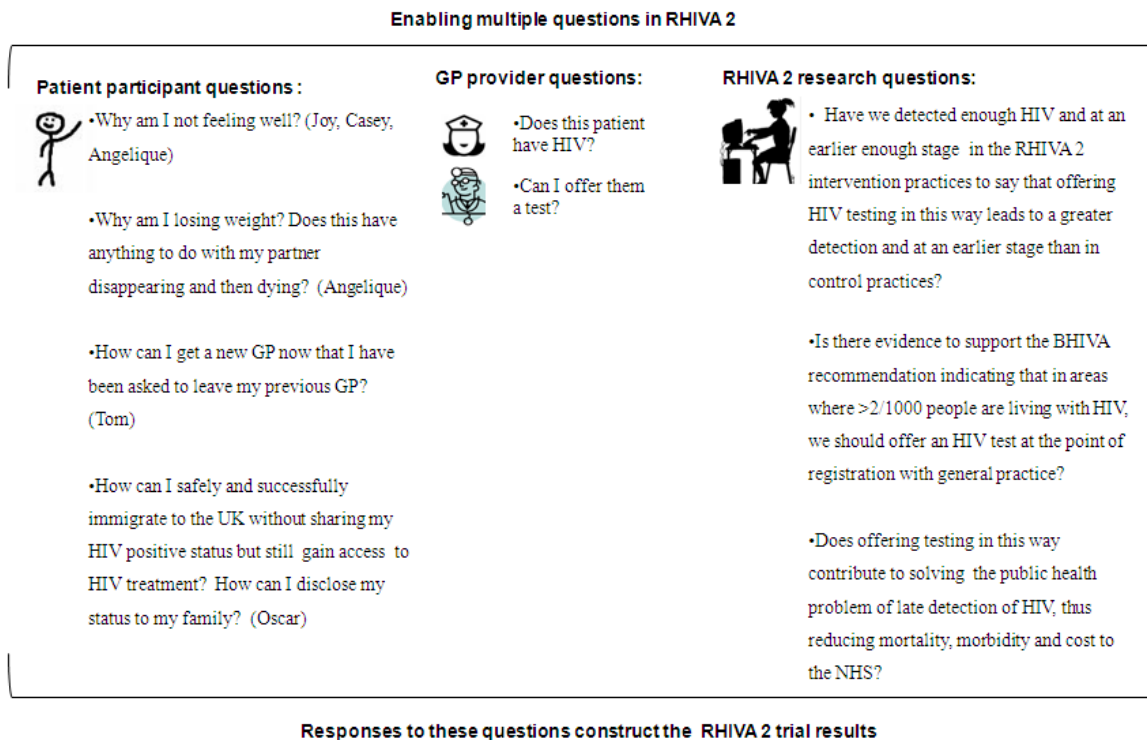


## 11.5 Discussion

*How did the intervention become meaningful for patients?*

In the form of experimentation outlined by Despret, when the desires of the researcher and those of the research subjects overlap, there is an opportunity for the experiment to become meaningful (Despret, 2008). What becomes apparent through the exploration of patient cases is how patients sought answers to various questions through RHIVA2. Joy, Casey and Angelique had health concerns. Angelique also wondered if her ill health was related to her former partner's disappearance, she persisted for answers to the point of being offered rapid HIV testing, and so gained entry to the trial. Tom wanted to resolve his logistical health care issue, he had not moved boroughs but needed to register with a new practice after being asked to find a new GP. Oscar wanted to know how he could safely enter and remain in the UK without disclosing his HIV-positive status. RHIVA2 enabled him to do this, while also giving him an opportunity to disclose his status to his family. In attending to their own questions some patients inverted the assumed relationship of the patient to the trial and transgressed the trial logic. The RHIVA2 trial becomes effective when patients can resolve questions or problems through the intervention and this enables the trial results. When the desires of the research intervention overlap enough with the desires of the patients the results can take hold. The Figure below outlines some of the multiple questions being asked through RHIVA2.

**Figure 13.** Enabling multiple questions in RHIVA2



*How did the results take hold (?): Generalisability ‘bit by bit’*

Inspired by Despret’s concept of ‘attunement’ between research and participants as a lens to consider what took place in the accounts provided to enable the trial to ‘work’? it is clear that in some cases strict inclusion criteria was forgone, for example, patients who were not new and not HIV negative were included in the trial. This was done through the actions of the health care providers and by the patients themselves and may represent an occasion of ‘attunement’.

The trial in this case was also an intervention, this meant that the trial acted and was enacted in multiple ways. That patients encountered the research as ‘care as usual’ aligns with the pragmatic design of the trial but also produces an equivocation, where the trial is being enacted as an intervention while also being an evaluation. Potentially as a result of the trial being enacted in the ‘real world’, at times strict inclusion criteria was forgone, for example

including patients who were not new, perhaps not able to agree to a test, and not HIV negative. The setting and the individuals allowed for experimental attunements. The space enabled by the pragmatic design allowed for attuning between patients, providers and the intervention. Despret's description of how generalisability was determined (in Pepperberg's parrot study) indicates how the experimental apparatus can enable similar outcomes with different parrots replete with their own attunements and overlapping desires. Despret describes this idea below:

'Consequently, this generalization bit by bit, from success to success is no longer expressed in terms of what parrots are, but in the terms of the possibilities that the apparatus could actualize. Generalisation has changed sides: it is no longer on the side of parrot neither on the side of the researcher, who ought to represent an anyone guaranteeing objectivity: now it qualifies the appropriate apparatuses.' (Despret, 2008: p.128).

With RHIVA2 being open enough to allow for the entrance of different patient questions and to be resolved with the experimental device, generalisability is developed 'bit by bit'. A form of intersubjectivity is determined between the trial, the intervention and the patients, where intersubjectivity is considered as:

'becoming what the other suggests to you, accepting a proposal of subjectivity, acting in the manner in which the other addresses you, actualizing and verifying this proposal, in the sense of rendering it true.' (Despret 2008: p.135).

In RHIVA2, loose inclusion criteria here, a potential solution to a patient problem there, aggregate to create results that hold and create RHIVA2 participants, despite potential non-coherence. Following the description of intersubjectivity above, the patients are able to accept the role of research subject offered by RHIVA2 and render the results true, despite having their own potentially challenging questions and identities. The concepts introduced here will be further explored in the following chapter, related to the pragmatic clinical trial.

The patient cases demonstrate that a good intervention and a good experiment is one where patient meanings are enabled and patient questions attended to. Post diagnosis, good care appears to attend to patient subjectivities and the multiplicity and specificity of HIV. I will describe how the work of normalisation and the role of specialist services interacted with what patients felt was 'good' for them.

### *The paradoxical work of normalisation*

The ‘normalising technology’ of screening allows patients such as Oscar, who is experiencing HIV quite exceptionally (fearing deportation, coordinating his own medical management), to treat his HIV in a way that enables him to achieve his goals without needing to disclose his status. Casey, who would have never gone for testing, despite being in a high risk group, is able to access testing without needing to make a specific appointment. Here ‘normalising’ HIV is successful particularly because HIV is experienced exceptionally. However, the support for this version of normalisation, which centres general practice and screening approaches, does not carry through in the same way post-diagnosis. Here, participants find specialist services more ‘normalising’ than general practice, as services that attend to the multiplicity and specificity of HIV infection and both the biomedical and identity impacts of the infection allow patients to experience HIV as ‘less of a big deal’. So while the conclusions of RHIVA2 promote a greater role for general practice in HIV detection and care, this is only partially supported by the patient data. ‘Normalising’ testing is helpful in obtaining diagnoses, however it appears that specialist services are preferred from this point onward.

### *Specialist services: Aligning multiplicity, attending to specificity and acknowledging patient experiences*

In specialist services, the multiple understandings and experiences of what an HIV infection may be appeared better attended to and to some degree aligned. Various clinical indicators, specificities of disease transmission and manifestation, treatment regimes etcetera are determined in specialist care and attending to patient narratives appeared central in this work of alignment.

Rita Charon describes medicine as requiring narrative competence, defining this as ‘the ability to acknowledge, absorb, and act on the stories and plights of others’ enabling of ‘more humane and effective medical practice’ (Charon, 2001: p.1897). In regards to diagnosis, a narrative may enable the construction of meaning, supply useful analytic clues or categories, encourage empathy and understanding between clinicians and patients as well as be a form of

experiencing illness for the patient (Greenhalgh and Hurwitz, 1999). In further describing the role of narrative in health and illness Greenhalgh and Hurwitz state:

‘Episodes of sickness are important milestones in the enacted narratives of patients’ lives. Thus, not only do we live by narrative but, often with our doctor or nurse as witness, we fall ill, get better, get worse, stay the same, and finally die by narrative too. The narrative provides meaning, context, and perspective for the patient’s predicament. It defines how, why, and in what way he or she is ill. The study of narrative offers a possibility of developing an understanding that cannot be arrived at by any other means.’ (Greenhalgh and Hurwitz, 1999: p.318).

What was evident in the data was how the form of delivering HIV testing in RHIVA2 (rapidly and in the new patient health check) limits the possibility for a personalised interaction with the patient. To a degree this was the point of the complex intervention tested in the RHIVA2 trial, to wrap HIV testing into a screening approach for which a risk factor history, or the request for an HIV test is not required, an active avoidance of a personalised and narrative based approach. While this may have enabled testing in some cases, it impacted participant impressions about services. Casey and Tom describe their experience of specialist services in the quotes below:

‘I just feel comfortable. They’re always nice, they smile. Some of them remember me and say hello. They just don’t make it seem like a big deal. ‘Just going to take your blood, see you later’ . . . it’s not a big deal when I come here at all. The only person really freaking out is me and other than that, they’re always happy to talk to you if you’ve got anything...if you need to talk about travel insurance, there’s a brochure somewhere there.’ (Casey)

‘It’s everybody and they work together. They care and they treat you as an individual, and it’s been reassuring, because it’s not easy to deal with this, particularly after a lifetime of fearing it.’ (Tom)

Often, general practice is seen as a site where the ‘life world’ (Greenhalgh et al., 2006) of the patient can be better encountered and explored and as a space more amenable to the practice of narrative based medicine and ‘person-centered generalist care’ (Reeve et al., 2013: p.1). As patients described their experiences of primary and secondary care services, there was a preference to receive care in specialist HIV settings. This preference related to the participants’ experience of HIV as ‘not normal’ for them and a space specific to HIV better attended to this, as well as the identity effects of an HIV diagnosis. Complicating the logic of ‘normalisation’ this appeared achieved in the following way: By having a service that was

specialised to HIV, replete with clinicians who encounter HIV regularly it allowed patients to see it as '*less of a big deal*'. HIV appeared to be experienced less exceptionally in a service specialised to HIV than in a general practice where HIV remains a 'big deal'.

## **11.6 Conclusion**

Broadly a narrative, personalised medicine approach appeared to take place in the specialist setting a setting attentive to the specificities of HIV allowed patients to experience it as 'less of a big deal', whereas the test procedure in the GP practices was designed to be run as a technical process driven by a strict algorithm. While in the first instance it may appear that this relates to the mechanism of test offer (rapid, new patient), it became apparent that this preference extended beyond this into the importance of a service with specialist HIV knowledge, extensive experience with HIV- positive individuals and a culture and ethos of acceptance, affirmation and friendliness. The specificities and relational aspects of HIV infection were acknowledged in this setting and the individual's complexity better realised and attended to.

Historian of science, Charles Rosenberg describes how 'we are never illness or disease, but rather, always their sum in the world of day to day experience' (Rosenberg, 2002: p.258). As seen in this chapter, results between biological indicators and subjective realities are constitutive of the trial results. While we may rely on health bureaucracies to connect us to spaces, techniques, personnel and onwards to enable us to live, attention to disease discourses and the practices they engender remains necessary so as not to be 'fragmenting and alienating' forces in managing an individual's relationship to larger society (Rosenberg, 2002: p.258).

Normalising HIV within health bureaucracies and for populations at large may be strategic, but for individuals normalcy may remain variable and individually defined. This was borne out in the findings of this chapter, where a population screening approach aiming to normalise HIV resulted in the achievement of broad public health objectives and allowed individuals to interact with their potential HIV infections in ways that generated diagnosis. But, for individuals, post-diagnosis, HIV felt most 'normal' in specialised settings

that could attend to the more situated aspects of disease with varying anomalous realities for an individual.

The findings presented above shed further light on the patterning of experience by the logic of normalisation and the experimental logics of the pragmatic trial. The patient case studies reveal how normalising HIV testing may allow individuals to gain answers to a variety of subjective questions of a health, logistical, migration and relational nature. The trial becomes meaningful to patients and therefore constitutive of the results in its ability to respond to these subjectivities. In the following Chapter, I take a closer look at the logic of the pragmatic trial, synthesising findings from across parts 1,2 and 3 gaining greater insight into the RHIVA2 ‘difference machine’.

## Chapter 12: CONSIDERATIONS OF THE PRAGMATIC TRIAL

### 12.1 Introduction

*‘Simply engaging with the complexity of people’s lives and desires – their constraints, subjectivities, projects – in ever-changing social worlds constantly necessitates the rethinking of our theoretical apparatuses. What would it mean for our research methodologies and ways of writing to consistently embrace this unfinishedness, seeking ways to analyse the general, the structural, and the processual while maintaining an acute awareness of the inevitable incompleteness of our theories?’*  
(Biehl and Locke, 2010: p.320)

Thus far in the thesis I have explored the justification and enablement of the HIV screening policy under investigation, its impact on general practice organisations implementing the policy as a part of a pragmatic trial of rapid HIV testing, and the impact of the policy on patients testing HIV-positive as a part of the trial. Throughout, I have attended to the two stories that inform this thesis: Story 1: the logic of normalisation implied in the HIV screening intervention; and Story 2: the logic of the pragmatic trial, the mechanism of implementation and evaluation for RHIVA2. I have developed a picture of the RHIVA2 trial as a complex situated event with manifold effects on the involved populations and organisations. I have offered evidence to support the argument that participant accounts of diagnosis as a part of the trial ruptured some of the assumptions embedded in the trial logic. In this chapter, which is focused on the pragmatic clinical trial more broadly, I seek to complicate the picture further through a more theoretical consideration of the findings. It is here that Story 2: the logic of the pragmatic trial will be most developed.

In this chapter, I focus specifically on the trial method and consider the broad case study presented within this thesis. I aim to consider data from a large-scale synthesis of methods which ‘work(s) to understand the macro without reducing or bounding the micro’? (Biehl and Locke, 2010: p.336). Findings from the various sub-studies are considered alongside the results from the RHIVA2 trial, in order to draw out the wider implications for the assertions of generalisability and reproducibility implicated in the pragmatic trial design. My goal in this chapter is to question the pragmatic trial as a device aiming to measure what is commonly thought of as both the scientific (for example, the establishment of causality through the statistical links between interventions and outcomes, and the control of



confounding variables) and the social (for example, the role of context and behaviour) in measuring the ‘real world’ of ‘everyday’ practice.

### *The pragmatic trial*

*‘By accommodating the human unpredictability attendant to the ‘real clinic’, the pragmatic clinical trial locates its evidentiary context between the rigour of an experimental protocol and the specificities of the health care environment.’ (Kelly, 2008: p.7)*

The value and promise of the pragmatic trial lies in its claim to successfully integrate the ‘social’ into a randomised controlled trial logic, to account for contextual factors while still providing the standard of transferability desired by the evidence based medicine paradigm (Kelly, 2008, 2010). As discussed in Chapter 8, the RCT is valued for its alleged ability to reduce bias and produce objective, reproducible, generalisable and robust results, as well as determine causal pathways. In many ways, the responsibilities assigned to the pragmatic clinical trial are more far-reaching than those of its forefather, the RCT, because the pragmatic trial contains not only the measures of efficacy (does X work under ideal experimental conditions?) ideally demonstrated by the RCT but also attempts to establish effectiveness (will X work **here?**), the outcome desired by policy makers, public health professionals and all those aiming to determine how the intervention might hold up in a ‘real world’ full of context. Broadly, the pragmatic trial aims to explicitly account for social practices in ways the traditional RCT does not (Kelly, 2010). While efficacy demonstrates the integrity of the effect in ideal conditions, effectiveness asks how it performs in its context of use. Kelly argues that these ‘models of “everyday practice” embed experimental protocols in the clinic’ (Kelly, 2008: p.4) and as a result the pragmatic trial simultaneously ‘implements the evidence it produces’ (Kelly, 2008: p.4).

As a result, the pragmatic trial design and those enacting it have a number of responsibilities in their attempts to demonstrate effectiveness; they aim to realise multiple objectives simultaneously. They must adhere to the logics of the randomised controlled trial design and its positing of a discoverable, measureable reality that is objective and transferable. But they should also effectively account for the messy and contingent interactions of individuals,

technologies, cultures, material practices, illnesses and more. Pragmatic trial designs are expected to combine these substantial demands in a demonstrable way that adheres to predefined protocol; is feasible for, and reflective of, 'everyday' practice; and is implemented in a way that is acceptable to patients and providers (ideally with their explicit involvement) (Kelly, 2008, 2010; Wills and Moreira, 2010). In the case of RHIVA2, it was through the trial mechanism that national policy was implemented and evaluated. Clearly, these public experiments (Kelly, 2008) are complex, active and productive events.

### *Complexity, context and the promise of generalisability*

In response to the calls for a greater understanding of complex interventions and techniques for evaluating them, authors have suggested a reconceptualising of 'context' and 'complex'. Cohn et al, in '*Entangled complexity: why complex interventions just are not complicated enough*', challenge the use of the term complex, arguing for a more 'ecological' approach and a reconsideration of the aims of fidelity and reproducibility (2013). They challenge hierarchies of evidence that unreservedly promote the randomised controlled trial design, particularly for interventions that are explicitly outside the laboratory and are acknowledged as 'complex' and situated in the 'real world' (Cohn et al., 2013). In their view this mechanistic approach to complexity, where researchers are encouraged to reduce phenomena to their component parts, misses the dynamic, integrated and emergent nature of many interventions and inappropriately attributes causality and claims of fidelity and reproducibility as a result.

Hawe et al. also call for a greater theorisation of complex interventions. They question the role of 'standardisation' and ask 'could one of the reasons for the interventions not working be that the components have been overly standardised?' (Hawe et al., 2004: p.1561). In promoting openness and higher-order thinking their calls relate to the proposition by Cohn et al. that suggests a more ecological approach where social processes, such as those being measured in complex interventions, are emergent and situated (Cohn et al., 2013). Hawe et al. propose that aligning fidelity conceptually, prioritising function over form might allow for more successful measurement of social phenomena and enable environment to respond and

adapt (Hawe et al., 2004). The approach suggested by Hawe et al., however, could be seen as an example of ‘tinkering’ with RCT logic to better ‘capture’ the real and not put into question enough of the assumptions made by the RCT. By tinkering with design aspects while retaining the RCT logic one could suggest these authors have not challenged the underlying ontological assumptions of a pragmatic trial, an issue other authors have tried to tackle more directly.

### *‘Situated Efficacy’*

Critical work on the randomised controlled trial and its claims by sociologists Savransky and Rosengarten explores RCT logic and problematises RCT ontology. They propose the concept of ‘situated efficacy’ in considering our contemporary experimental and evaluative models.

At a conference at the Brocher Foundation in 2015, Rosengarten and Savransky explored the RCT and concepts of efficacy and effectiveness ontologically through the work of metaphysician and pragmatist Alfred North Whitehead. They proposed that the ‘RCT and its ‘evidence’ are epistemologically and ontologically different from what has earned it the status of ‘gold standard’ for evidence based medicine.’ (Rosengarten and Savaransky, 2015: p.1). The authors take issue with the idea that contingency is placed external to interventions and how the intervention remains static while the external determines its effects (Rosengarten and Savaransky, 2015: p.2). The authors suggest that interventions are always situated and participate in the active construction of the effects. In proposing the notion of ‘situated efficacy’ they reconceive of research as:

‘a milieu of objects and relations shaping each other in complex but also varying ways, it becomes possible and indeed necessary to abandon the presumption of objects with distinct causal effects and, hence, that the task of isolation is valid and enables future prediction.’ (Rosengarten and Savaransky, 2015: p.3).

These authors have recently published a paper that takes these ideas further, including further insights on the pragmatic trial (2016). They frame their overarching question as ‘what is nature capable of’ and aim to ‘reclaim questions of ontology in biomedical cultures and

practices' (2016: p.1). Emphasising their view of the pragmatic trial as a situated achievement, they suggest what is required is:

‘an ethos that, in resisting clear-cut bifurcations between “the essential” and “the accidental”, “the biological” and “the social”, “the natural” and “the cultural”, may become oriented towards the construction of new, inventive, plural, and always partial descriptions and proposals concerned with the question of what the *realities* of health and disease are made of’ (Savransky and Rosengarten, 2016: p. 4).

What the authors appear to be moving towards, is the consideration of research designs that acknowledge the processual nature of reality, bodies and interactions and that accept speculation and uncertainty as inherent and potentially helpful in research despite the challenges they present to trial principles such as generalisability and fidelity. The approach proposed by Savransky and Rosengarten may better align with post-positivist understandings of ‘the real’ and may work to recognise some of the ontological tension that may be encountered in the pragmatic trial logic.

### *Partial / Multiple / Enacted*

In another approach to reconciling accounts of the real, theorists propose partial views and encourage explicitly situated accounts of events (See Haraway, 1999; Mol, 2002). The dominant conception of ‘objectivity’ is also challenged (Haraway, 1984).

In her article ‘*Situated knowledges: The science question in feminism and the privilege of partial perspectives*’, Donna Haraway discusses conceptions of objectivity and proposes how to integrate more embodied accounts, which acknowledge ‘historical contingency for all knowledge claims and knowing subjects’ but that also have a ‘commitment to faithful accounts of a “real” world’ (Haraway, 1984: p.280). She proposes a doctrine of ‘embodied objectivity’, a feminist objectivity she entitles ‘situated knowledges’ (Haraway, 1984: p.581). This sits in contrast to a positivist ontology which proposes ‘self appearing’ knowledge and universal claims (Goldenberg, 2006). For Haraway, all knowledge is situated and aligns with other post-positivist views that there is never knowledge that is not known in some way by

someone (Hastrup, 2004). Haraway develops the character of the ‘modest witness’ to ascribe the positivist ontological claims (Haraway, 1996). This witness is imbued with

‘a distinguished epistemological and social power concealed by modernist ideals of “rationality”, “objectivity”, and “value neutrality”. His modesty guarantees his legitimacy as an “authorised ventriloquist for the object world, adding nothing from his mere opinions, from his biasing embodiment. And so he is endowed with the remarkable power to establish the facts. He bears witness.’ (Haraway, 1996: p.429)

Haraway goes on to propose that ‘objectivity turns out to be about particular and specific embodiment and definitely not about the false vision promising transcendence of all limits and responsibilities.’ (1984: p.583). She argues for ‘situated and embodied knowledges and (an) argument against various forms of unlocatable, and so irresponsible, knowledge claim’ (1984; p.583). Here irresponsible means ‘unable to be called into account’ (Haraway, 1984: p.583). She describes her views on objectivity, and the role of partiality in making responsible knowledge claims the quote below:

‘I am arguing for politics and epistemologies of location, positioning, and situating, where partiality and not universality is the condition of being heard to make rational knowledge claims.’ (Haraway, 1988: p.589)

Annemarie Mol also suggests the importance of multiplicity and a re-thinking of ontology in her work, *The Body Multiple*, discussed elsewhere in the thesis (section 10.1.2). The point made by these authors is that there may be multiple, though not limitless, interacting realities, each of which is constituted through the processes of enacting and performing the object (Mol, 2002; Blackman, 2008).

### *Situated versus generalisable*

A theme emerging in the literature considered for this chapter has been the problematising of a scientific ‘view from nowhere’ which underpins positivist biomedical discourse in general and the design and reporting of RCTs more specifically. The numerous micro practices, decisions and contexts of success in the trial are concealed. Summaries of numbers, assumed to be reproducible if certain aspects of the protocol are followed, are foregrounded while the dynamic and ecological processes that produce results and contribute to ‘evidence’ are played down (Cohn et al., 2013; Goldenberg, 2006). Of interest to various theorists is what is at stake when knowledge claims are removed from the situations of their creation, their contexts

or socio-temporal locations? The pragmatic trial design can be seen as a move towards acknowledging the impact of social processes and practices on the evaluation of interventions and in some ways a destabilising of the positivist ontology assigned to trials. Yet, in retaining the logic of the RCT how far can this move travel?

In the case of the pragmatic trial, one might ask: To what extent are the findings of a pragmatic trial situated in context to a degree that limits their possibilities for external applicability? How do our experimental devices conceal the productive work of such experiments in a way where particular yet integral accounts would be occluded?

In the case of RHIVA2, even when the trial is successful (in the sense of producing statistically significant findings), and we can also report contextual detail on the mechanisms through which these results were achieved, to what extent should the published findings be viewed as situated and contingent as opposed to generalisable and reproducible? While it is beyond the scope of this PhD to attempt to answer this question in full, in this chapter I will briefly explore some theoretical approaches to the question in relation to data emerging from my overarching case study.

To illustrate my findings, I will present two ‘ambiguities’. Ambiguity 1: *Interpreting RHIVA2’s ‘active ingredients’* was uncovered during the provider-level study when interviewing practice staff about their experience of RHIVA2. Ambiguity 2: *New for whom? ‘Diagnosing’ Oscar* was encountered while interviewing a patient who tested HIV-positive through rapid testing. He was introduced in Chapter 11. I will now describe my methodological process.

## **12.2 Methodological orientation**

In undertaking the qualitative work that informs this PhD, it was not my initial intention to explicitly explore the pragmatic trial design. Whilst I began with some questions about what the method occluded, I was increasingly struck by how central the pragmatic trial logic

became as the empirical and analytic work unfolded. A chapter on the pragmatic trial itself emerged as a key component of my findings. Each sub-study complicated the picture of what the pragmatic trial was producing outside of what had been predefined as “the results” in the trial. Accordingly, a synthesis of data and methods produced the findings presented here.

Hastrup discusses knowledge as organised information which is by nature reductive and selective: ‘it is reductive because it renders empirical complexity and messiness in clear, but therefore also more limited, propositions about the world’ (Hastrup, 2004: p.456). In RHIVA2, only particular information gained status as data and this was selected based on the pre-established outcome measures and informed by the trial logic. As discussed in Chapter 3, this PhD explores the ‘surplus’ of information that never gained status in the trial. However, what has been reduced and selected as data here also requires explanation, see this quote by Hastrup:

‘Evidently, when it comes to analysis and writing, a sense of closure must be attained; the network must be “cut”, so to say (Strathern, 1996), in my terms implying a temporary objectification of relational knowledge, from which others may then proceed – provided they are satisfied about the soundness of the argument.’ (Hastrup, 2004: p.458)

The main methods used in this chapter are autoethnography and case study (see Chapter 4 for a description of these methods). Here I call upon anthropological ways of knowing, which privilege explicitly relational accounts, reflexivity and a synthesis of various data forms to produce a hopefully compelling account of a research event. The data presented consists of unique events and once-occurring acts (Hastrup, 2004) and would struggle to conform to any positivist idea of evidence. This approach valorises ethnographic data and aligns with what Anne Kelly describes in the quote below:

‘Conventionally, medical anthropologists reconcile the pragmatic and theoretical dimensions of their work by focusing their ethnographic attention on the practices, experiences and understandings that medical knowledge excludes. Illustrative in biomedicine in context, ethnographic data reveals the contingent and site-specific relations invisible to the universalizing and purifying gaze of medical science.’ (Kelly, 2010: p.3)

The literature outlined above which argues against singularity and a positivist ontology informs this chapter and my choice of how to ‘cut’ the data and make a knowledge claim. The aim of this chapter is not to suggest a more ‘real’ account of the trial, but is to explore other ways of understanding and interpreting the research event which allows for speculation about alternative conceptualisations. The findings presented point to openings for such consideration.

### **12.3 Method**

The object in this case is the pragmatic trial; the findings appeared to me as ruptures in the operating trial assumptions. In describing abduction, Locke et al. outline a concept that resonated with my experience of encountering these findings. Describing Czarniawska’s ideas, they write:

‘abduction in research as much like detective processes, involving the recognition of puzzling observations that enable us to discern and construct new plots. She emphasizes that the process does not entirely conform to the scientific method, but instead involves a certain amount of mystery about how method produces the outcome’ (Locke et al., 2008: p.908)

Abductive reasoning relies on emotion, surprise, doubt and confusion to generate a process of inquiry and search for ideas to suggest possible means of reconciling the emotions, to generate ‘belief’ and produce a resolution (Locke et al., 2008). To get at an explanation for the findings presented here, and this sense of ‘belief’ and ‘resolution’, a deeper understanding of ways of knowing was required and a move towards theory which deals in ontology and epistemology felt necessary. Locke et al. describe Van de Ven’s view that abduction begins with an anomaly or surprise, which motivates researchers to sustain inquiry (Locke et al., 2008). This also relates to the case study literature, for example in how Flyvberg describes the Popperian principle of falsification, where ‘what appears to be “white” often turns out on closer examination to be “black” (2006: p.11). The experience of encountering a ‘black swan’, so to speak, is conceivable as first registering as a feeling of surprise, doubt or concern.



### *The analytic process*

My analytic approach draws on the analytic autoethnography method as well as case study. This analytic approach (described in section 4.2) is evident through evidence of the five aspects of autoethnography described by Anderson (2006). First, participation as a ‘complete research member’; I was the RHIVA2 trial manager. Second, analytic reflexivity; as demonstrated throughout the thesis and undertaking the PhD. Third, narrative visibility; I describe my experiences in first person narrative with explicit reference the subjective dimensions of my involvement. Fourth, dialogue with informants beyond the self; demonstrated in my undertaking of interviews and membership in the trial team. And finally, a commitment to theoretical analysis; expounded in this chapter.

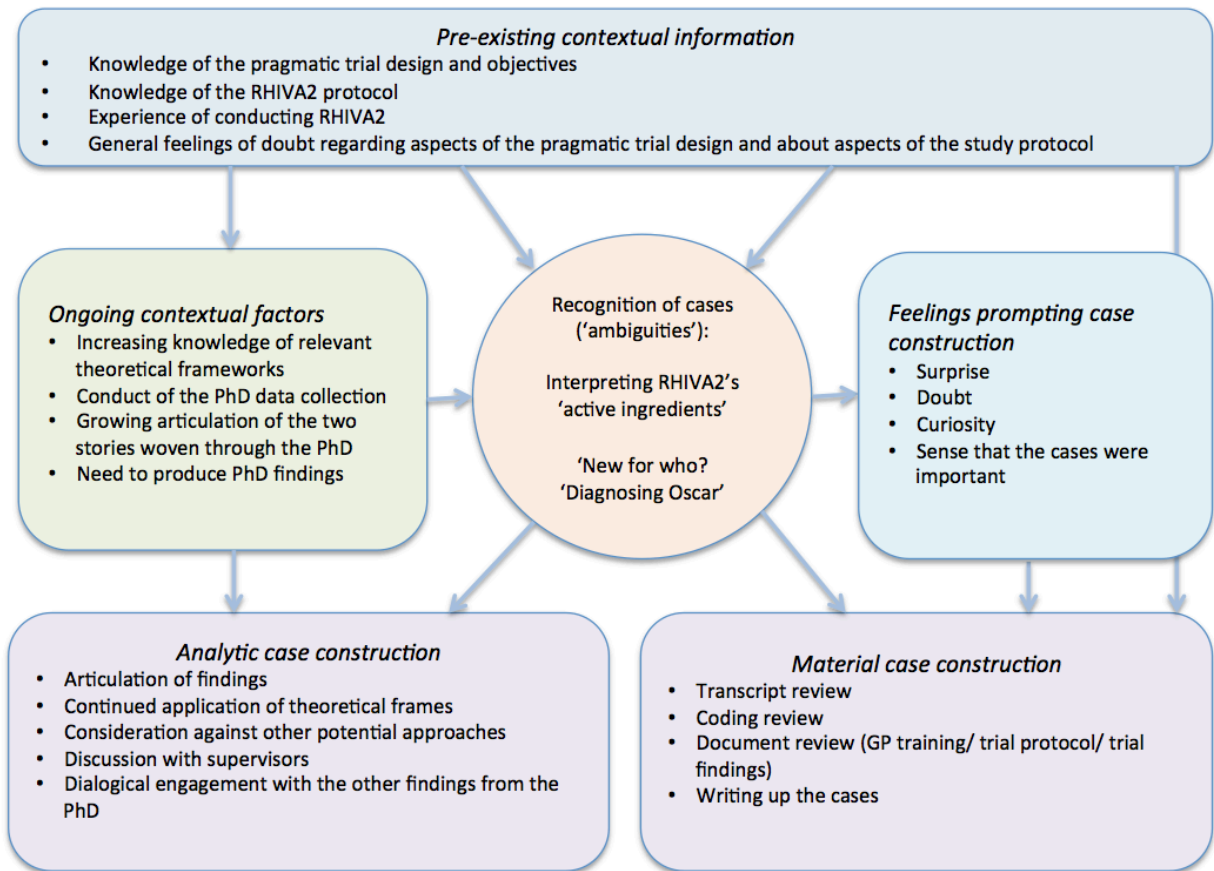
### *Case construction*

The construction of the two cases presented here called on a variety of data sources. These are listed below as well as in Figure 13 where I visualise my analytic process.

Within each of the two cases (‘ambiguities’) put forth as findings for this chapter I call upon the following:

- My initial queries about the inclusion criteria for the trial. (See upcoming Box 2)
- The experience of negotiating the ‘accompanied patient’ aspect of the training with the trial team (see upcoming Figure 14.).
- My experience of delivering training to RHIVA2 intervention practices in my role as research assistant and trial manager.
- Analysis of the trial protocol.
- Knowledge of the RHIVA2 results.
- Qualitative interviews with patients and providers.
- Conversations with trial team members.
- My ongoing reflections on the trial.
- My feelings of surprise and doubt while undertaking the qualitative research and encountering the two cases presented.

Figure 14. Encountering ‘ambiguity’ 1 and 2



## 12.4 Findings

### *Ambiguity 1: Interpreting RHIVA2's 'active ingredients'*

During a qualitative interview in the provider level sub-study, one of the clinicians began discussing his experience of two HIV-positive rapid testing events, revealing that in both cases the patient did not speak English and attended their new patient health check accompanied by a friend or family member who acted as an informal interpreter. An interview in the patient level sub-study also revealed another individual diagnosed in this way. As a result, it became apparent that at least two and possibly three of the 11 patients diagnosed through rapid testing as a part of the trial were non-English speakers and began

their diagnostic journeys with the assistance of informal interpretation by a friend or family member.

Below, the aforementioned health care professional discusses one of the cases where a reactive result was received by a non-English speaking accompanied patient.

‘This patient came from [European Country], a [X] year old boy and the mother was interpreting. We asked all the questions for physical ... he was qualifying for the Chlamydia as well because he was under [X]. Then I said leave your urine and let’s do the blood. He was afraid of the needle and the mother said, ‘No, you should take it.’ We did it and it came two dots, sharp, right and this was the first time this happened so I thought I had to get this book [referring to trial instruction booklet] to see the algorithm and then I called the doctor. The interpreter was there and she was the mother and...so I said I need to find out, I’m having a doubt about the test, that’s what I said to him so let me go verify it with my colleague. I talked to him and he said that’s it, that is positive and because this is the test that is coming up positive, we’ll have to do the blood test to confirm positive or negative but by and large it’s positive. Mother was ok to understand what I say but I said while we are here, you should explain it to your son in the presence of us so we know the information passed, otherwise you don’t know. Then she explained. I thought he was a little bit anxious, he became anxious when this happened and then he said ok.’ (Health care provider at RHIVA2 intervention practice)

The same health professional goes on to discuss another non-English speaking patient who was offered testing through the interpretation of a friend accompanying him to the new patient health check.

‘The second one, he was [from the Americas] but came from [European country] with his passport. The friend was interpreting. He came along...he was feeling weak.’ (Health care provider at RHIVA2 intervention practice)

Unsure that the friend was able to adequately translate the result of the rapid HIV test, the healthcare professional booked the patient in the following day with formal translation to conduct the confirmatory venous blood tests.

‘When [it is] the registration time, we don’t bother that much about troubling with the interpreter or we will be wasting time but when we did the venous blood, we booked the interpreter the next day, then we can explain in very professional language so the interpreter came in. Because his English wasn’t that great [referring to the friend

acting as interpreter], then [the interpreter] can explain everything so that's why we call the interpreter next when we're doing the venous blood.' (Health care provider at RHIVA2 intervention practice)

The first young man discussed was initially reluctant to have the rapid HIV test. While the hesitation is cited as a fear of the finger-prick, it is possible there are other reasons he was not eager to accept testing, with his mother acting as interpreter. He went on to have confirmatory venous blood testing immediately and never used formal translation services at the surgery.

The second patient was accompanied by a friend who it appears was able to translate the initial new patient health check and the offer of the rapid HIV test, including the receipt of a reactive test result. However, the clinician was unclear as to whether he had effectively communicated the result to the patient and so arranged for a follow-up appointment with official interpretation for the next day where they would conduct the required confirmatory venous blood testing.

### *Context of importance*

I explicitly asked about accompanied patients when interviewing providers as a part of the organisational level study. This was an aspect of testing that worried me and I recognised it as an area where site-specific divergences in practice were likely. My concern stemmed from a lack of clarity in the study protocol and my view of best practice in HIV testing. Having worked for years in sexual and reproductive rights, I understood that HIV testing should not be offered to an individual in a setting where they may not be able to make a full, free and informed choice. Offering someone testing in front of a friend or relative may place an individual in a difficult position where this right may not be recognised. Yet, I acknowledged that there were ethical concerns around *not* being offered a HIV test. If we were offering HIV screening and excluded non-English speakers, they were receiving a different standard of care than other patients, for example. The delivery of the test upon registration and the rapid nature of the device meant requiring formal interpretation would mean booking a separate appointment, compromising key aspects of the trial and likely also requiring arrangement with the informal interpreter. In this scenario, the HIV test would not be

integrated in the new patient check and would represent a greater cost and work load for the general practice, and patients opting to attend an additional appointment for a new patient check may differ from other patients being offered the intervention. My concerns began when reviewing the inclusion criteria for the trial and designing the GP training. The trial inclusion criteria are indicated in Box 3 (highlighting my own):

**Box 3:** Inclusion and exclusion criteria for patients in RHIVA2

#### 1.1 Inclusion criteria for HIV POCT

\* Individuals aged 16 years or older registering at study practices

\* Individuals able to undertake the pre-test discussion in English or with the use of a suitable translator

\* Individuals with unknown HIV status.

#### 1.2 Exclusion criteria for HIV POCT

\* Age under 16 years

\* Individuals with limited English abilities, who are unable to understand the info sheet or, who are unable to engage with the pretest discussion for HIV testing

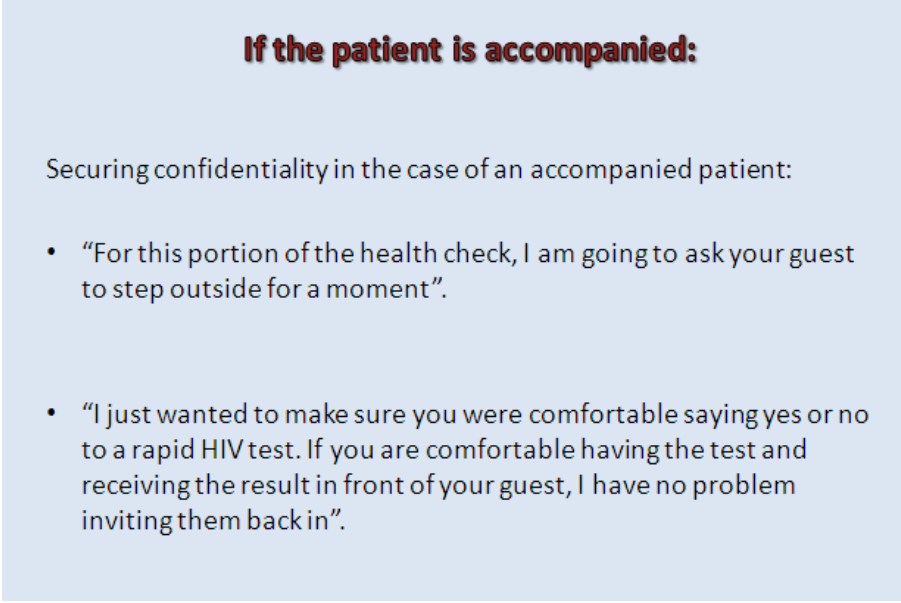
(Leber et al., Effectiveness of HIV screening in primary care: A cluster RCT and economic analysis: Study Protocol. Version 5.1, August, 2012).

Indicated in the criteria is that in the case of non-English speaking patients, a ‘suitable translator’ is required to offer testing. At no point in the protocol or during the training, is the term ‘suitable’ delineated. I also noted that while the inclusion criteria mentioned a ‘suitable interpreter’, the exclusion criteria focused on the lack of English skills and ability to engage with trial materials and not on the ‘suitability’ or interpretation.

Keen to enact fidelity to the pragmatic nature of the trial and a replicate ‘everyday practice’, while acknowledging potential ethical implications, the team eventually settled on the following approach: We would recommend what we thought best practice was, and then

suggest that clinicians use their clinical judgement, experience and expertise. In the GP training session we included a short discussion about managing accompanied patients, eliciting views and experiences while sharing the slide visualised in Figure 15.

**Figure 15.** Slide from GP slide deck relating to accompanied patients



**If the patient is accompanied:**

Securing confidentiality in the case of an accompanied patient:

- “For this portion of the health check, I am going to ask your guest to step outside for a moment”.
- “I just wanted to make sure you were comfortable saying yes or no to a rapid HIV test. If you are comfortable having the test and receiving the result in front of your guest, I have no problem inviting them back in”.

(RHIVA2 GP training slide deck version 11. 2011)

The phrasing provided suggested that whenever possible patients should be offered testing privately. How this could be enacted in the case of an individual who spoke no English whatsoever and was dependent on the friend or family member, however, remained unclear. In an attempt to improve uptake and mitigate language barriers, patient information sheets were provided in 10 languages spoken locally<sup>10</sup>. The languages were determined upon consultation with local nursing staff in intervention practices.

Data collected for the trial did not include collecting the number of accompanied patients tested or how often an interpreter was used. Whether or not a patient tested as part of the trial could speak English was unknown to the trial team. Trial findings were reported without discussion of the frequency of use of interpretation, or how accompanied patients were managed throughout the trial. My qualitative interviews revealed diverse preferences for the

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<sup>10</sup> We began with four languages, English, French, Vietnamese and Turkish but expanded upon request of nurses in participating practices to include Portuguese, Bangladeshi, Spanish, Romanian, Polish and Chinese.

management of accompanied patients and limited English speakers by providers of rapid testing. Some did not offer the test to accompanied patients at all, while others used their discretion and had personal thresholds, such as not offering testing if a minor was doing the informal interpretation.

Important to the pragmatic trial method is the mimicking of ‘everyday practice’ in the delivery of the intervention being tested, which informed our interpretation of the term ‘suitable’ from the protocol. However, if it is recommended best practice that when results from pragmatic trials are presented the intervention should be described in sufficient detail to enable replication and be applicable to other like settings (Zwarenstein et al., 2008). The example of informal interpretation described above demonstrates how key the interpretation of the term ‘suitable’ was not only by the trial team, but by individual clinicians, in delivering the RHIVA2 trial results. Informal interpretation is clearly an ‘active ingredient’ and key mechanism of the intervention but was not recognised as such in the trial logic. A further delineation of the term ‘suitable’ or a change in the ethical approvals to only offer tests using formal interpretation services may have substantially altered the trial results, altering statistical significance, and produced different conclusions about the impact of rapid testing for HIV in primary care. With no discussion or acknowledgement of the role of language in the trial reporting it could be argued that the results are less easily reproducible or generalisable and an understanding of causal mechanisms is in question. The range of behaviours reported by clinicians in offering tests to accompanied patients demonstrates a lack of predictability in offering tests under these circumstances. While the variable interpretation of the term ‘suitable’ could be seen to align with the pragmatic tone of the trial and we see the effective enabling of ‘the social’, in that broad social practice was enacted, there are implications for the potentially contrasting principles of rigour, standardisation, fidelity and reproducibility.

When the protocol was open enough to allow providers to act as they would in the ‘real world’ more cases of HIV were detected than for example, if this interpretive approach to offering HIV tests to accompanied patients had been closed down by ethical or practical dimensions that limited the offer of tests. This leads one to question how far the success of the trial’s pragmatism travels and whether this impinges on other trial principles which help achieve the high status of this study design in the hierarchy of evidence. In regards to Story 2

of this thesis -the logic of the pragmatic trial- the finding described above highlights some of the tension inherent to measuring ‘the scientific’ and ‘the social’.

### ***Ambiguity 2: New for whom? ‘Diagnosing’ Oscar***

‘Thus, the trial participants would demonstrate the beneficial effects of the program by acting as functional elements of the program itself. Their relationship to patient populations would not be merely epidemiological; the pragmatic clinical trial would secure the representative nature of the research sample through a series of complex experimental moves that cultivated and coordinated the technical and human aspects of clinical practice.’ (Kelly, 2008: p.9)

While undertaking the patient level study, another instance that inspired a feeling of surprise, doubt and ongoing consideration was encountered. Oscar, who was introduced in the previous chapter and who tested positive for HIV with rapid testing in RHIVA2 also poses challenges to the trial logic. The aforementioned RHIVA2 inclusion criteria indicated that patients who are known to be HIV-positive should not be offered a rapid HIV test. The inclusion criteria are reproduced in Box 4 (emphasis added).

#### ***Box 4.*** RHIVA2 inclusion criteria with emphasis on HIV status

##### 1.1 Inclusion criteria for HIV POCT

- \* Individuals aged 16 years or older registering at study practices
- \* Individuals able to undertake the pre-test discussion in English or with the use of a suitable translator
- \* **Individuals with unknown HIV status.**

##### 1.2 Exclusion criteria for HIV POCT

- \* Age under 16 years
- \* Individuals with limited English abilities, who are unable to understand the info sheet or, who are unable to engage with the pretest discussion for HIV testing



The onus was placed on the patient to indicate their HIV status on what was theoretically their first visit to the surgery for a 10-minute registration health check. Eighteen of the patients diagnosed in the trial were found to be on record with the Genitourinary Medicine Clinical Activity Data Set as having had a prior HIV diagnosis in the UK (Leber et al., 2015). Accordingly, these individuals were discounted from the overall trial results. Oscar however proves an exception. Aware of his HIV-positive status for approximately a decade, Oscar was a non-English speaking new immigrant to the UK. As a result he had never had an HIV diagnosis in England and was therefore unlikely to be listed on the PHE system. As discussed in Chapter 11, Oscar had been very concerned about his ability to successfully enter and remain in the UK, so much so that with the help of his former HIV consultant in a nearby European country, he planned the discontinuation of his HIV medication and aimed to be re-diagnosed here in the UK, seemingly for the first time. He felt that this would reduce his risk of deportation and increase his ability to access free healthcare. Oscar describes his decision in the quote below:

‘Yes, they asked me for my consent in order to do some tests on me; blood, urine, to find out what the state of my health was, and they said this test would check for HIV and I gave my consent, because I knew that I had it and I knew...I wanted them to know but I wasn’t brave or courageous enough for them to find out because I came from another country and I was, I was scared that the country wouldn’t accept me.’  
(Oscar)

Through the offer of HIV testing as part of the new patient health check Oscar did not need to raise the possibility of HIV testing with his general practice. He was able to re-enter HIV care in the UK at an early opportunity, when registering in primary care services. He used the trial and its opt-out nature to effectively conceal his HIV status from health services until he had effectively entered the UK medical system and secondary care services.

### *Context of importance*

Whether Oscar, as a new diagnosis in the context of the UK, achieves the objectives of the trial raises interesting questions. Does Oscar’s diagnosis *count* as a new diagnosis *here*? Oscar was presented as a new diagnosis in the trial results and contributed to the overall positive and statistically significant trial findings despite being HIV-positive for over a

decade. Clinically, and in terms of UK population statistics Oscar can ostensibly be a new diagnosis, he is new to the NHS and a new migrant. For the primary outcome of the trial: ‘mean CD4 count of newly diagnosed patients’ (Leber et al., p.2), it is feasible that Oscar would have impacted the outcome calculations, as his previous adherence to HIV medications may have altered his CD4 count, if high this may have reflected his use of HIV medication and certainly was not an indication of early detection. For the secondary outcome of the trial, ‘rate of new diagnosis (patient’s diagnosed/year/10,000 practice list size)’ (Leber et al., 2015: p.2), it may be that Oscar’s nominal contribution to the outcome of the trial holds, as his may be considered a new diagnosis in the context of the UK medical system. As discussed in the previous chapter and linking to Ambiguity 1 about interpretation, Oscar alone subverts many trial assumptions. His consultation was not only interpreted by a family member, he was also already HIV-positive, challenging trial inclusion criteria.

Annemarie Mol suggests that we pay attention to the effects of our interventions, beyond those intended (Mol, 2002). Oscar is demonstrative of the many ways in which technologies and interventions can produce the unintended and go far beyond the result we hone in on. Perhaps this is obvious. Many trialists would readily indicate how aware they are that trial results do not tell the ‘whole’ story and that rich stories lie behind much of the trial data. While it would be easy to conclude that the trial erred by not detecting this ‘false’ new HIV diagnosis, the conduct of the trial in this case adhered to protocol and was enacted in line with trial practices. There is no practical way of determining if patients are actively concealing their HIV status and a key assumption of the trial logic was that individuals align with how they present in services, that they live in the borough, are unaware of their status, are over 16 and so on. If patients are not upfront about their HIV status, cases like Oscar may be unavoidable. Nevertheless such examples have implications for trial results, including the numbers. Demonstrated here is research subject agency and innovation that challenges the way subjects are positioned and represented by the trial. The linearity and compliance assigned to research subjects in the trial logic is challenged and the role of the trial in generating particular forms of patients becomes more apparent as was also demonstrated in previous chapter. Oscar’s case disrupts trial assumptions with implications for the findings. The ‘surplus’ here is rich and instructive as well as potentially problematic to the trial results.

## 12.5 Discussion

‘Since each diagnostic outcome diverges from others, the idea of gold standards may get undermined rather than strengthened. And if each therapeutic intervention achieves something different, what counts as improvement may similarly tend to become less obvious. The question ‘is this intervention effective?’ then dissolves into another question: ‘what effects does it have?’ (Mol, 2002: p.183)

The final RHIVA2 trial paper published in *The Lancet HIV* indicates: ‘we excluded patients who could not understand the information sheet or engage the pretest discussion for HIV testing, and those who were HIV-positive.’ (Leber et al., 2015: p.1). Interpretation and translation is not mentioned in the paper as it was not considered key in describing the intervention. Patients testing positive for HIV and on record as previously diagnosed in the UK were excluded from the final analysis (Leber et al., 2015). The point explicated in this chapter is not that the RHIVA2 trial findings are incorrect but a larger consideration about what can be understood about the enactment of interventions with the pragmatic trial method. Ambiguity 1 and 2 reveal the pragmatic clinical trial as a productive but tricky device that in some ways is successful at merging the ‘gold standard’ methods of the RCT design with the complex and situated social world of everyday clinical practice. Yet the method is unable to account for this effectiveness within the restrictive evaluation and reporting methods commonly operationalised in the pragmatic trial logic. While the method is designed to produce definitive and generalisable answers to complex research questions about the ‘real world’, in reality, findings may be contestable and much is occluded. The method limits what can be seen and therefore reported on, affecting our understanding of the truly effective mechanisms and interactions at play in a ‘successful’ intervention, raising questions of how deeply situated events and their accounts can effectively be translated to other locations, with their own sets of situated aspects (Savransky and Rosengarten, 2016).

I now suggest three theoretical perspectives on the findings. I first explore the concept of equivocation, espoused by Viveiros de Castro (Viveiros de Castro, 2004), as one way in which the results may be ‘taking hold’ in practice. I then consider Mol’s ontological politics (Mol, 1999), as a potential way of working with some of the tension described in this chapter. I finish with the work of Savransky and Rosengarten, exploring the ontological aspects of the pragmatic trial device (2016).

## *Equivocal spaces*

One way in which to consider the findings is through the concept of ‘equivocation’.

On the entirely different matter of Amerindian perspectivism in the article ‘*Perspectival Anthropology and the Method of Controlled Equivocation*’, Eduardo Viveiros de Castro presents the concept of ‘equivocation’ and its role and importance in anthropological reasoning (2004). For Viveiros de Castro, intercultural equivocation emerges in attempts for translation, in the acts of comparison of anthropologies between two groups, which he describes as a central task for the anthropologist (2004). He is concerned with how to acknowledge that anthropologists and the groups they study are in comparative intellectual operations, and how to ‘configure the people as theoretical agent rather than as passive subject’ (Viveiros de Castro, 2004: p.2). Here, equivocation is the ‘referential alterity between homonymic concepts’ and the ‘mode of communication par excellence between different perspectival positions’ (Viveiros de Castro, 2004: p. 3). It was this passage by Viveiros de Castro which compelled me to consider the findings through a lens of equivocality:

‘An equivocation is not just “a failure to understand” (*Oxford English Dictionary, 1989*), but a failure to understand that understandings are necessarily not the same, and that they are not related to imaginary ways of ‘seeing the world’ but to real worlds that are being seen.’ (Viveiros de Castro, 1994: p.9)

‘Controlled equivocation’, he suggests, may open spaces to allow this. He describes ‘the space of equivocation’ in the quote below:

‘To translate is to situate oneself in the space of the equivocation and to dwell there. It is not to unmake the equivocation (since this would be to suppose it never existed in the first place) but precisely the opposite is true. To translate is to emphasize or potentialise the equivocation, that is, to open and widen the space imagined not to exist between the conceptual languages in contact, a space that the equivocation precisely concealed. The equivocation is not that which impedes the relation, but that which founds and impels it: a difference in perspective. To translate is to presume that an equivocation always exists; it is to communicate by differences, instead of silencing the Other by presuming a univocality- the essential similarity-between what the Other and We are saying.’ (Viveiros de Castro, 2004: p.8)

In opening and widening the space ‘imagined not to exist’, Viveiros de Castro could be seen as suggesting an encounter with difference imagined or presumed not to be present. While

Viveiros de Castro goes on to delineate an advanced theoretical concept<sup>11</sup> related to anthropology, however, reading his work inspired thinking around the comparison and interpretation of research events. If controlled equivocation is one method of interrogating the differences between people's cosmology, for example, what emerges when variable accounts from different methods of the same research event are compared? Could these be considered moments of equivocation? And how might the equivocal space be opened up and explored? That is moments and spaces in which interpretations about the meaning of certain research events are settled in one way in spite of the fact that they concurrently also mean something else.

Perhaps the issue of interpretation for accompanied, non- English speaking patients could be seen as a form of equivocation. The trial understands the intervention to be complete as it is described in the protocol and in the final trial paper, significant and ripe for reproducibility and generalisability. However, a key mechanism in the obtaining of the significant results, the testing of non-English speaking patients with informal interpretation, goes unrecognised by the trial method, was not collected as data and therefore goes unnoticed and unreported. **As a result, the intervention passes as successful while represented as one set of actions and outcomes, but enacted as another.** In other words, the intervention is equivocal. The RHIVA2 intervention as described in the study protocol and the trial findings paper (without the acknowledgement of informal interpretation) is understood as what produced the results. However, could informal interpretation be essential to the intervention in producing the trial results? Here, the intervention passes as one understanding while being enacted as another. The 'looseness' around 'suitable' interpretation and the lack of understanding of what the trial is enacted as in practice is occluded through the pragmatic trial logic but encountered when explored through methodologies which consider other forms of experience as data.

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<sup>11</sup> Viveiros de Castro is careful to designate that 'equivocations' are not error or cases of 'linguistic incompetence, ignorance of context, lack of personal empathy, indiscretion, literalist ingenuity, commercialization of information, lies, manipulation, bad faith, forgetfulness, and sundry other deformations or shortcomings that may afflict anthropological discursivity at an empirical level. In contrast to these contingent pathologies, the equivocation is a properly transcendental category of anthropology, a constitutive dimension of the discipline's project of cultural translation.' (Viveiros de Castro, 2004: p.10). For this reason I assert that reading Viveiros de Castro's paper on equivocation inspired new ways of considering the findings but is not a theoretical lens that has been applied in full to the data as it is possible that some of what is described in the cases presented may also be considered as what is described in the quote above, such as a lack of knowledge of context, for example.

### *Working with incommensurability: Ontological politics*

‘A politics-of-what assumes that the end points of trials, the goals sought for, are political in character. But there is more. Interventions have other effects, too. They bring about more than they seek to achieve. In current practice, trials deal with a few of these, so-called side effects. Usually they take one or two calamities into account’ (Mol, 2002: p.155)

In some ways there is a link between the concept of ‘equivocation’ and that of ‘multiplicity’ and multiple ontologies as proposed by Annemarie Mol. Opening up equivocations could be seen as a way of bringing multiplicity into view. In the act of comparison where equivocations are explored, it could be said that different ontologies are encountered. Mol’s concept of ‘ontological politics’ may be one way of working with the potential incommensurability encountered in such a space.

In concluding her praxiography of disease, Annemarie Mol calls for ontological politics (Mol, 2002), a term she elaborates in the paper ‘*Ontological politics: A word and some questions*’ (Mol, 1999). She describes ontological politics as a composite term:

‘It talks of ontology – which in standard philosophical parlance defines what belongs to the real, the conditions of possibility to live with. If the term ‘ontology’ is combined with that of ‘politics’ then this suggests that the conditions of possibility are not given. That reality does not precede the mundane practices in which we interact with it, but is rather shaped within these practices. So the term politics works to underline this active mode, this process of shaping, and the fact that its character is both open and contested’ (Mol, 1999: p.75)

In response to the proposition of a multiplicity of disease and the inability to determine one singular reality she calls for a ‘politics of what?’

In attending to some of the inadvertent effects of the trial, it becomes apparent that the trial logic presents a singular account of the research event and other versions may interfere. Instead of trying to determine which is ‘the more real’, Mol would suggest interrogating our

values as researchers and acknowledging that many versions exist with differing effects. She describes how this raises new questions for researchers in her quote below:

‘The new normative question therefore becomes which of these interferences are good ones. And when, where, in which context, and for whom are they good. Good knowledge, then, does not draw its worth from living up to reality. What we should seek, instead, are worthwhile ways of living with the real.’ (Mol, 2002: p.158)

Such an approach might make very explicit the role of early consideration of the objectives, values and claims of any research study. Researchers would need to clarify their ontological positions, rationale for a trial design, and image of the research problem or otherwise and perhaps consider that the study results may always be partial and one of many possible accounts. To propose that a research team can sit down and establish which reality they want to uncover, as it may seem is being suggested is overly simplistic. There is an assumption that such choices are apparent, that there are a set of singularities to choose from, that the object under study is not interlinked inexorably with other objects, and that the unintended effects Mol cautions us to be wary of are not limited (Mol, 1999). Despite these theoretical limitations, taking Mol’s proposal into account, I suggest, could ease some of the ontological tension present in the pragmatic trial design and enactment. By opening up the pragmatic trial to include some of the surplus (unintended effects) and acknowledging that other versions of the research event (multiplicity) represent potentially important accounts while promoting an earlier and broader consideration of the desired effects of our ‘interfering methods’ (ontological politics) may do better at accounting for what takes place in a pragmatic trial. My sensitising concepts of *pragmatism* and *doubt* (Chapter 3), along with the concepts of partiality and multiplicity subsequently introduced throughout the thesis, could be seen to align with the pragmatist emphasis on abduction and speculation which ‘merely suggests that something *may be*’ (Locke et al., 2008: p.907; Simpson, 2009), and does not rule out other possibilities.

Opening this space for speculation and for the ‘surplus’ to be meaningful could lead us to alternative and potentially more helpful research outcomes. These ideas are summarized in relation to a trial design by Mol in the quote below:

‘A clinical trial in which the effectiveness of various interventions is assessed, can no longer be taken at face value. For another question must come first: what are the effects it should be seeking? Answers to that question are incorporated in the

information, but also in the techniques we currently live with. They tend to be implicit, entangled and inexorably linked up with the various performances of any one disease.’ (Mol 1999: p.86)

What is suggested here by Mol, resonates with some of what is proposed by Savransky and Rosengarten in their aforementioned paper, regarding the ‘pragmatic art of consequences’ (2016: p.1).

### *Ontological consequences*

In tackling questions of ontology as they relate to health Savransky and Rosengarten describe the problem of:

‘letting certain methodologies prescribe in advance what is and what is not relevant to understanding and intervening in processes of health and disease everywhere and always, despite the not infrequent difficulties such directives encounter in becoming effective in concrete situations’ (Savransky and Rosengarten, 2016: p.1).

This resonates with the findings described above. In some senses the pragmatic trial closed down on the pragmatic work of the trial through the assigning of a predetermined protocol, intervention definition and final outcome measures. This meant that despite what took place in practice, what would be measured and what would count as ‘data’ was already decided, without any space for emergence, or in the words of Savransky and Rosengarten, without any space for other ‘consequences’ to be considered. What interests the authors is the:

‘possibility of developing an ontological intervention as a pragmatic art of consequences...of speculating on the possible consequences of imagining alternative images in which the realities of health and disease can prompt novel understandings, where the evidence produced by biomedical methods might acquire different meanings, and where other forms of knowledge, of evidence and of ignorance may be integrated.’ (Savransky and Rosengarten, 2016: p.1).

In suggesting that those working in biomedical research ‘venture into situated forms of learning, understanding and intervening’, it appears that the authors suggest a loosening of the grip the mechanistic ontology of the RCT and evidence-based medicine have on describing worlds of health and disease and entertain other considerations of ‘what nature is capable of’ (Savransky and Rosengarten, 2016: p.6).



Ambiguities<sup>1</sup> and 2 presented here within represent an attempt to consider what is required by the ‘hold’ of the pragmatic trial logic and what is at stake as a result. The findings have implications for the conclusions of the trial, the potential for reproducibility and generalisability of the trial results and for the pragmatic trial method more broadly. Since the publishing of the RHIVA2 trial results in the *Lancet HIV*, a definitive and closed story of RHIVA2 appears to have been presented and the ‘surplus’ sewn up; the evidence, so to speak, is complete. The pragmatic trial is a productive experiment that generates more effects than the logic of the pragmatic trial acknowledges. While tinkering with the trial design may be suggested as a way of overcoming what may appear as poor articulation of the research outcomes or an ill-informed choice of what data to collect, I suggest such a critique does not address a more fundamental issue. The example of informal interpretation in RHIVA2 illustrates a more theoretical issue. The data suggest that how the ‘real world’ imagined in the pragmatic trial logic is investigated necessitates an occlusion of inherently emergent, situated and contingent phenomena which are integral to producing the trial results. Treating ‘the social’ as a set of quantifiable, static factors which can be effectively parsed, measured and reported places these social facts into an evidence based medicine paradigm. While such phenomena may be considered more broadly in the case of a statistically ‘insignificant’ trial, where a statistically significant result has not been obtained, in the findings presented here it becomes clear that even when the trial is statistically significant and the protocol understood as broadly reproducible key events constituting the significant results are occluded.

Savransky and Rosengarten provocatively describe the ontological assumptions of evidence-based medicine or of any claim to the real as a ‘fiction’ (2016: p.6). The RHIVA2 trial findings describe a reality that aligns with the mechanistic ontologies required by the RCT design. However, dialogical engagement with other ontological assumptions and evidence gathered through contrasting methods reveals the trial conclusions as partial, as an act of ‘temporary objectification for relational knowledge from which other may proceed’ (Hastrup, 2004: p. 458). Just as I have parsed a particular story from the experience of the phenomena that was RHIVA2 through the methods and orientations described here, the final trial paper is a similar artifact. This raises the question of what I suggest regarding the interpretation of the RHIVA2 trial findings. The proposal here is not a discrediting of the RHIVA2 findings, for all intents and purposes the trial was enacted according to the protocol and tenets of the

method and in the contemporary biomedical realm the results hold. The point is broader, and relates more to the engagement with evidence. The grip the RCT and its mechanistic ontology appear to have on research in health and disease and the silencing power such methodological results place upon the ‘surplus’, on what is produced with other modes of inquiry and what can be considered with differing ontological engagements, has consequences.

## **12.6 Conclusion**

In exploring these findings I have outlined how the logic of the RCT does not acknowledge some of the work the pragmatic trial does in being ‘pragmatic’ in the philosophical sense. Exploring the experience of the trial with different methods and epistemological assumptions allows for differing accounts of the research event to come forward, which have implications for the claims of the pragmatic trial and the presentation of findings from the RHIVA2 trial. Aligning with alternative ontologies (Savransky and Rosengarten, 2016) or seeing ontology as multiple (Mol, 2002) or considering the pragmatic trial as a site of equivocation (Viveiros de Castro, 2004) may allow us to open up the trial logic in a way that allows for speculation and imagining alternative ways of thinking about the productive work of trial devices.

## Chapter 13: DISCUSSION

This final chapter offers overarching reflections on the work presented in the PhD. I begin with a summary of findings. I then reflect on the research process before discussing Story 1: the logic of normalisation for HIV and Story 2: the logic of the pragmatic trial. I end with recommended areas for further research.

### 13.1 Summary of findings

I began this PhD with a number of questions about RHIVA2, about evidence creation and about how we determine if interventions are effective or not. The multiple methods, theoretical frames, data sources and experiences called upon in the process of producing this thesis reflect my aim of moving beyond a singular presentation of the trial to consider other versions of the event and the questions they raise. I also aimed to consider the impact of providing HIV testing as done in RHIVA2 on practices, provider and patients. The findings reflect the complexity of evaluating ‘everyday practice’ and of screening for biosocial infections such as HIV, and suggest a deeper engagement with ‘the surplus’ is required.

*Part 1: Population screening for HIV and the logic of normalisation* presented findings from the policy-level study of this PhD. Through the analysis of 14 in-depth interviews with policy stakeholders and of four policy documents, a nuanced description of the policy setting was provided. In Chapter 6, through a combination of Kingdon’s policy windows theory and Wilson and Jungner’s principles for the early detection of disease a confluence of factors which enabled the 2008 National Guidance and therefore the RHIVA2 trial were described (Kingdon, 2003; Wilson and Jungner, 1968; BHIVA et al., 2008). Here, 17 themes were identified and categorised into four micro-streams: *epidemiology and public health, treatment, technology and techniques, the health setting and socio-cultural dimensions of HIV infection*. A policy window was enabled due to a merging of the problem stream and the policy stream. The policy problem was related to the late detection of HIV and the resultant effects on mortality, morbidity and health care spending. The policy stream offered population screening approaches for HIV, enabled by precedent setting policy in the UK and abroad, the growing role of general practice in HIV care and the changing nature of HIV infection with access to treatment and new technologies. Wilson and Junger’s early principles

for the detection of disease were broadly fulfilled, making the population screening approach epidemiologically justifiable. Kingdon's broad model was supported through the inclusion of micro-streams to enable a more nuanced discussion of the findings. The combination of Kingdon's model with Wilson and Jungner's principles was an effective theoretical frame for describing the factors enabling the recommendation in the 2008 National Guidance.

Analysis at the policy level continued in Chapter 7 with a discourse analysis of the policy maker interviews and four key policy documents. Three key discourses were identified as informing and upholding the population screening approach in general practice. Firstly, a *risk/surveillance discourse* positions the untested general population as the new risk site for HIV while justifying medical practices that bring this population into view, making the role of general practice more central (and that of HIV specialists less so). Secondly, a *discourse of normalisation* aims to treat HIV as a disease 'like any other' and new sites, forms and practices of HIV testing come into focus, again assigning general practice with greater responsibilities in HIV care. The third discourse, a *HIV generations and dynamism discourse* considers HIV as historically situated and dynamic, with multiple enactments that affect the policy language and justification surrounding HIV testing. HIV's variability and dynamism alters professional roles and identities while resonating with Mol's proposition of a multiple ontology of disease (2002). Part 1 of the thesis drew out Story 1: the logic of normalisation, and described how testing as done in RHIVA2 was justified and enabled.

***Part 2: RHIVA2 in practice: Implementing and evaluating a complex intervention*** explored the organisational-level study of the PhD through the application of a retrospective process evaluation using Greenhalgh et al.'s model of the diffusion of innovations in health care settings (2004). This analysis, presented in four organisational case studies (constructed with both qualitative and quantitative data), identified key characteristics of RHIVA2 intervention practices in their ability to implement the complex intervention of rapid HIV testing for new registrants. Practices with strong leadership, good managerial relations, readiness for change, a culture of staff training and sufficient time for the innovation were most successful at implementing rapid testing. If staff delivering the intervention believed that testing was valuable and were able to observe reactive test results they appeared more dedicated to using the rapid tests. Additionally, local adaptations to the innovation by practice staff to better suit

their work place routines facilitated implementation. The Greenhalgh et al. model proved an effective analytic tool for exploring and explaining the variability in rapid testing amongst RHIVA2 practices and also allowed for the exploration of the organisations' experiences of the trial. Uniquely, this was the first application of the model to a RCT of a complex intervention. Part 2 of the PhD saw the combination of Story1: the logic of normalisation and Story 2: the logic of the pragmatic trial combine on-site in 20 intervention practices. It is here that some of the tricky issues around the simultaneous implementation and evaluation of complex interventions aiming to produce rigorous scientific findings with 'real world' applicability came into view.

***In Part 3: Experimental end-points: Patient experience and the pragmatic trial***, the logic of the pragmatic trial was drawn out and patient experiences of testing HIV-positive with rapid testing were explored. In considering how the trial results were constructed five patient case studies were presented which traced patient subjectivities and interactions with both Story 1 and Story 2. In Chapter 11, through an exploration of experimentality and normalisation (Despret 2004,2008; Timmermans and Haas, 2008; Persson, 2013) RHIVA2 becomes meaningful to patients when the intervention is able to respond to patient questions – and these questions are very different for different patients. Forgone inclusion criteria for RHIVA2 and the normalisation technology of screening allows for patients to interact with testing in unexpected ways. Despite the declared success of normalised testing in general practice to enable patient diagnosis, post-diagnosis patients consider the specialist setting as (in many senses) more normalising.

In Chapter 12, I present findings related to the pragmatic trial method. Through a synthesis of findings from the PhD research I argue that while the pragmatic trial method enabled the results produced in RHIVA2, key mechanisms by which the results were produced were occluded by the logic of the trial device. Two 'ambiguities' are presented where trial inclusion criteria are questioned: the case of informal interpretation and the case of Oscar, a patient already living with HIV. Calling on theory from sociology, anthropology and science and technology studies I suggest that some 'active ingredients' producing the trial results are obscured due to the rationalistic ontology of the pragmatic trial compromising the RCT tenets of reproducibility and generalisability. By considering the experiment from a more enriched

theoretical perspective and the pragmatic trial in terms of ontology and ‘equivocation’, a unique perspective on the enactment of the pragmatic trial device was presented (Mol, 2002; Viveiros de Castro, 2004; Savransky and Rosengarten, 2016).

### **13.2 Summary of Limitations**

The broad work presented here includes a number of limitations. In Part 1, I explore the policy that underpinned the RHIVA2 trial. This guidance was issued in 2008 and in the fast moving HIV policy and public health community a number of changes have taken place between the issuing of the guidance, the conduct of the RHIVA2 trial and the presentation of this thesis. The views shared by the policy stakeholders interviewed are most likely impacted by these changes and it may have been that interviews undertaken at the time the guidance was issued would have revealed different views on the guidance and the work of RHIVA2. In Part 2, I retrospectively explore the application of the diffusion of innovations model to data from the trial. A prospective study using this design may have revealed different insights (See page 180). In Parts 1, 2 and 3 I call on interview data related to the policy, provider and patient level studies. While 23 interviews were undertaken in the providers study presented in Part 2, the choice to present the findings through the examples of four practices means that interviews from these practices were called upon more heavily than interview data from practices which were not featured as examples. Additionally, in Part 3, where I explore the experience of patients diagnosed HIV positive through rapid testing in RHIVA2, I call on five (of a possible 11) in-depth interviews with patients. While these interviews allowed for a rich discussion, they reflect only a small number of patients (See page 190). While I trained most of the providers of rapid testing in how to use the instant test kit as part of my role of RHIVA2 trial manager, I did not directly observe testing and did not witness the consultations where testing was offered. This may have provided different data and allowed for a deeper ethnographic engagement with the study.

Additionally, as discussed in Part 2 (See page 149) aspects of the diffusion of innovations model were not included in the analysis. As the innovation was rolled out as a part of research and therefore followed a recruitment protocol, division of practices into intervention and control group, and took place largely prior to my joining of the RHIVA2 team aspects of the diffusion of innovations model including ‘outer context’, ‘linkage’ and ‘communication and influence’ were not used in the analysis to the same extent as the other dimensions of the model (See page 149). ‘Outer context’ and ‘communication and influence’ for testing and for

the trial is also widely considered in Part 1 where I explore the justification for the trial in-depth. However, it is possible that greater consideration of these dimensions of the model may have impacted the analysis.

A further discussion of the limitations is wrapped into the reflections on Story 1 and Story 2 later on in the discussion.

### **13.3 Reflections on the research process**

#### *An interdisciplinary endeavour*

The work presented here is interdisciplinary. I have called upon various schools of thought and disciplinary traditions to produce the findings. Interdisciplinary work holds a much discussed and debated status in the social sciences (Callard and Fitzgerald, 2015; Barry and Born, 2013; Hesse-Biber, 2016). In their book: '*Rethinking interdisciplinarity across the social sciences and neurosciences*', Callard and Fitzgerald reflect on interdisciplinarity, largely in the neurosciences. They engage with the concept through reflexive exploration of their mutual experiences of attempting interdisciplinary academic work, calling attention to the proposed benefits of such endeavors, the difficulty in making such collaborations meaningful, the emotions generated in doing so and the ever-present power dynamics at play (2015). Andrew Barry and Georgina Born describe interdisciplinarity as an ideal and a promise to bring closer together society and science, to solve emerging global issues through new innovations and modes of accountability and to generate potential solutions to economic problems (2013). They aim to consider interdisciplinarity as a field with the potential to enable novelty and as containing multiplicity and difference (Barry and Born, 2013). Despite these ambitious potentials interdisciplinarity is also often described as highly problematic; fragmenting knowledge, straining relations, being overstated in its application and success and resulting in a sort of colonization of some disciplines by others in some settings (Callard and Fitzgerald, 2015; Hesse-Biber, 2016).

Hesse-Biber describes how many researchers describe their work as interdisciplinary when they are actually doing multidisciplinary research (2016). Interdisciplinarity, she states, involves 'tracing reasoning, and seeking multiple understandings' (2016: p.650). The

synthesis this requires means the interdisciplinary researcher experiences ‘what it is to *work the tensions*’ between disciplinary borders and Hesse-Biber describes how a truly interdisciplinary approach requires time, cooperation and an active commitment to reflexivity (2016: p.649). I believe the work presented here contains both the strengths and the limitations of an interdisciplinary approach. My PhD has benefited from understanding and experiencing the processes, mechanics and enactments of trial design and conduct, a history of working in public health on sexual and reproductive rights including HIV, engagement with theory from philosophy and anthropology and supervisors who are trialists, social scientists and general practitioners. While I hope this has allowed for a creative account of the findings, it also means that a complete and impenetrable thesis has been impossible (and undesirable) to produce. That there is not a singular and complete argument presented in this thesis in many ways aligns with some of the theoretical frames explored within, where partiality and multiplicity are held up as important approaches to reality and to scientific inquiry and singular, traditionally objective accounts are problematised aligning strongly with the feminist critique of evidence based medicine (Goldenberg, 2006).

It is also my hope that this PhD offers an account where different methods and analytical approaches have been mixed in a meaningful way. Some researchers describe how much mixed methods research presents findings produced from different modes of inquiry alongside each other without any meaningful dialogue between the findings produced by the diverse methods (O’Cathain et al., 2007; Hesse-Biber, 2015). While this question was not a major theme in this PhD, I have pondered the longstanding ‘incommensurability’ or ‘incompatibility’ thesis oft discussed in mixed methods research where it is proposed that methods cannot be effectively mobilized outside of their paradigms of origin, that methods contain ontologies and are constrained by them (Morgan, 2007; Hesse-Biber, 2015). Instead of aligning myself with the incommensurability thesis outright I have aimed to engage with it, exploring the paradigms and ontologies at play and attempting to move beyond potential ‘non-coherence’.

I have aimed to synthesise the findings of the trial and the case study (containing autoethnography, process evaluation, document analysis and qualitative interviews) in a nuanced and meaningful way (where insights on population screening approaches for HIV and the logic of normalisation and on the work of the pragmatic trial in accounting for context with an RCT logic); a way that reflects the contribution of knowledge produced by each mode of inquiry. In terms of the wider arguments included here (see Part 3), it is only



through this process that they could be called upon and produced. This led me to wonder if the reluctance of many scientists to work with different methods and data sources in this way reflects wariness towards ontological politics (Mol, 2002). Considering the pressures on applied health researchers, undertaking an ontologically engaged trial, for example, may not be straightforward, quick or likely to produce the form of findings desired in the current research climate.

Undoubtedly additional literature and theoretical frames could have been used and different conclusions drawn from the findings. A more positivist approach, for example, may have not questioned the ontological assumptions of the pragmatic trial and may have pitched the analysis at the level of methodological tinkering. At least in part, I have opted to consider RHIVA2 in a way which moves the thesis into a potentially less comfortable territory in relation to the scientific cornerstones of objectivity, bias, generalisability and onwards, experiencing this working of the ‘tensions’ described by Hesse-Biber. This has also meant that it has not been straightforward to answer what has proven to be an oft-posed question: *so, did the trial work?*

*So, did the trial ‘work’?*

Being an interdisciplinary researcher has presented challenges, including often feeling afloat in a sea of potential approaches and understandings of the phenomena explored here. Throughout the PhD I have been encouraged by colleagues to ‘pick a side’ (*‘So are you for the trial, or against?’ ‘What you have described is interesting, but did it work, is it right?’*). There was a push to either align with the trialists or take a more critical and constructivist view. Neither approach has felt entirely accurate, or adequately representative of what has been observed and learned in the course of this PhD. I maintain that the pragmatic trial design is useful and generates important knowledge about health innovations in practice, but I argue that the approach and interaction with the pragmatic trial device needs greater consideration. A potentially important contribution of the work presented here is how the theoretical and methodological insights were gained. It was not my initial intention to explore RHIVA2 in this depth. The move to theory felt imperative and a way of responsibly

accounting for the data I encountered. Multiple methods and theoretical frames were, ironically, one way of bringing coherence to what felt like increasingly disparate and potentially contentious findings. Rendering the multiple methods, findings and theories presented here into a readable, coherent thesis has been one of the greatest challenges (and hopeful achievements) in completing this work.

To answer the question of whether the trial ‘worked’ aligns with my reply to the overarching research question of the PhD, about whether the implementation of RHIVA2 through a pragmatic randomised controlled trial could be regarded as successful. My intuitive response would be: *sort of, but it depends*. This unsatisfying reply echoes what Helga Nowotny discusses in her book: *The Cunning of Uncertainty* (2016). My type of answer, she describes, is not one people like, it is not neat or conclusive and effortlessly transformed into a fact that can travel and be easily deterministic for policy and politics. Nowotny describes the collective will for clear answers and decisive moments as a general ‘human craving for certainty’ (Nowotny 2016: p.13) and how in a fast-paced, increasingly connected and information laden world certainty may become ever more appealing. Nowotny encourages us to gain comfort with uncertainty, citing its cunning, unpredictable and consistently vacillating qualities as here to stay and the parallel impulse towards the definite as potentially unhelpful. Instead of providing certainty my reply to ‘did the trial work?’ inspires more questions: for whom, in what way and so on, highlighting once again this tricky issue of ‘context’, situated findings and understanding who is asking and why.

### *On false dichotomies: Implementing a normalised HIV with a hybrid evaluation device*

Throughout this thesis I have woven together two stories, Story 1, about the normalisation of HIV and Story 2, about the logic of the pragmatic trial. The decision to frame the thesis in terms of two stories reflects an attempt to make a complex landscape coherent. Rendering an event as complex as the RHIVA2 trial coherent, and distilling the themes and findings presented here has been a challenging task. The two stories are a constructed split and such false dichotomies have been an informal theme throughout the thesis. The ‘social’ and the ‘scientific’ have at times been conceptualised separately; evaluation and implementation

pulled apart while happening simultaneously; the normal versus the pathological in HIV; the ‘self’ in contrast to the molecular body and onwards. In practice these bifurcations sometimes hold and other times dissolve. Throughout the thesis I have considered categorisation (into included versus excluded patients, into the two logics described, for example) as performative and organisationally essential but also as a potentially problematic and awkward social practice with varying aims. In drawing attention to this point I reiterate the partial and constructed nature of the findings presented here and acknowledge that other stories could have been told and the phenomena spliced differently.

### *Reflections on ethics*

Undertaking this work involved the negotiation of various dimensions of ethics. In describing the research events care was taken to anonymise participating practices and individuals and written informed consent was obtained from all participants. I undertook patient public involvement activities throughout the project and presented my findings in a variety of settings including academic fora, community organisations and professional trainings and conferences.

At times I felt a dissonance between the trial and the PhD project. Uncovering some of the findings described within this thesis was not straightforward as I was proud and loyal to our work on the trial but also wanted to describe cases such as Oscar in an intellectually honest manner, which required putting some trial practices into question. Undertaking work nested in a large team study while aiming to produce a thoughtful account of the data my independent PhD project was producing was a challenge. This meant sometimes straddling various commitments as a key trial team member but also a social science PhD student and negotiating potential ethical dilemmas from a variety of perspectives. What I have presented here, I reiterate, is not meant to be read as a critique of the RHIVA2 trial as such but to shed light on the work of the pragmatic trials more broadly.

I will now provide final reflection on the two stories framing this thesis before considering areas of further research.

### 13.4 Reflections on Story 1: The normal and the pathological at once

#### *Aligning a disease picture for HIV*

‘This way of thinking about disease – the vision of abstracted disease entities as ever more precise mirrors of nature – has become extraordinarily pervasive, yet in its very explanatory power, it has posed a variety of intractable social dilemmas, problems that in fact underline the cultural centrality and ubiquitousness of contemporary disease concepts’ (Rosenberg 2002: p.251)

Historical and sociological work on disease and diagnosis reflects widely on how disease can be categorised or classified (Rosenberg, 2002; Löwy, 1992; Jutel and Nettleton, 2011; Timmermans and Haas, 2008). Within this work, HIV occupies a less contentious space than some other disease phenomena subject to screening. Cervical cytology, for example, where stages of potential disease are delineated and searched for has been explored and held up as an example of an emerging way of considering disease and infection, as in waiting, with indicators and markers that may or may not progress into life threatening illness and therefore ripe for surveillance (Singleton, 1998). It is broadly accepted that one *has* HIV *or not* and while some behaviours determine a risk profile for contracting the infection there is not an inborn biological predisposition or pre-disease state to be detected. In some senses this simplifies the diagnostic task which despite its ‘collective, cumulative and contingent process’ is still widely considered a ‘discrete act taking place at a particular moment in time’ (Rosenberg 2002: p.256). Aligning understandings of HIV presents challenges. The diagnostic event cues a corral of associations and disease pictures along with bureaucratic events containing diverging social and natural histories of HIV infection. When treated, HIV can lose or at least suspend some of its hallmark characteristics: infectiousness, lethality, a steady spiral into worsening health, and yet, one is definitively HIV-positive.

Rosenberg outlines four potential problems with our current definitions of disease and diagnosis. These include: ‘enforcing norms and defining deviance’, ‘fitting idiosyncratic human beings into constructed and constricting ideal-typical patterns, patterns necessarily abstract yet, in individual terms, paradoxically concrete’, the creation of proto-disease and disease states and finally, the bureaucratic imperative (Rosenberg, 2002: p.251). By proto-disease and disease states, Rosenberg refers to a category of disease in waiting, as

increasingly detected through screening practices, and the difficulty in giving such a state parameters. By the bureaucratic imperative, Rosenberg describes how nosological tables, protocols, infrastructures and disciplines surrounding disease interact and create disease and cannot be separated from contemporary understandings of what disease is and how it is experienced and enacted (Rosenberg, 2002). He goes on to describe the ‘central of diagnosis’ as linking the individual to the social system which is ‘necessarily a spectacle as well as a bureaucratic event’ (Rosenberg, 2002: p.255). Some of this tension in the quote below:

‘This is another area of maladjustment or difficulty of fit, not, from this perspective, the fit between the individual patient and the generalized disease picture but between a reductionist, mechanism-centered understanding of disease and a collective strategy for defining and maximizing health.’ (Rosenberg, 2002: p.254)

The justification of the policy of HIV testing for new registrants in general practice areas highly endemic for HIV calls upon both a normalised and a dangerous HIV. The acceptability of rapid testing and of the population screening approach relates to contemporary, medicalised HIV in the UK, where with access to medication HIV is treatable, potentially non-infectious and resembling more a chronic disease than a lethal infection. Despite this, much of the urgency and impetus for the detection of HIV relies on the historic framing of HIV in social movements and the understanding of HIV as infectious and deadly. Neither approach is wholly inaccurate or accurate, as untreated HIV remains infectious and lethal, while treated HIV may be non-infectious with ever growing prospects for survivorship. What becomes apparent is the operation of multiple HIVs, enacted as such from the policy through to interactions with patients, while the logic of normalisation works to bring new practices, sites and understandings of HIV into being, as described in Part 1 and throughout the thesis.

The work presented herein demonstrates that biological survivorship does not translate into a lived ‘normalcy’ for many patients and while treating HIV ‘normally’ by offering screening may allow individuals to access testing more easily, it does not extend to a preference for generalised care once diagnosed. Specialist HIV services which attend to specificity and align the multiplicities of HIV were preferable for patients involved in this study. The use of the term ‘normalisation’ for HIV may be unhelpful. While the aspirations of the logic include reducing stigma and streamlining health bureaucracy, it appears that pushing too hard for ‘normalisation’ also crowds out some of the important experiential and identity related

impacts of being HIV-positive. In general, the idea of a ‘normal’ illness goes against much contemporary and historical understandings of what it means to be ill.

Perhaps it is best to consider what could be a good way to test for and live with HIV for each individual, dependent on their ever-shifting biological, identity and social circumstances. Illness is perhaps best regarded as always situated in a dynamic, temporal interplay containing the specificities of disease but always in interaction with individuals and in a particular setting. Despite this, following both Rosenberg (2002) and Mol (2002), diseases can be seen as multiple, ontological entities within themselves, existing outside of and within individuals and constituting diverse social realities.

### **13.5 Reflections on Story 2: Experimentation and speculation, more possibilities for the pragmatic trial**

As described in Part 3, some philosophers of science acknowledge the importance of openness and a degree of indeterminacy to allow experimental systems to produce results of interest and remain relevant (Savransky and Rosengarten, 2016; Rheinberger, 1994). As discussed in Chapter 11 Hans-Jörg Rheinberger, the German philosopher of the life sciences, discusses the ability of experimental systems to produce difference and novelty as essential. Citing the work of Gilles Deleuze, he describes difference and repetition (the title of one of Deleuze’s most classic texts), as the driving force behind experiments (Rheinberger, 1994). Essential, according to Rheinberger, is for the experimental system to be a ‘generator of surprise’ (Rheinberger, 1994: p.167). In the quote below he describes experimental systems in temporal terms:

‘Research systems, with which I am concerned here, are characterized by a kind of differential reproduction by which the generation of the unknown becomes the reproductive driving force of the whole machinery. As long as this system works, the system so to speak remains ‘young’. “Being young”, then, is not here a result of being near zero on the time scale; it is a function if you will of the functioning of the system. The age of such a system is measured by its capacity to produce differences that count as unprecedented events and keep the machinery going’ (Rheinberger, 1994: p.68).

The findings of the PhD demonstrate the pragmatic trial as containing more potential to generate insight and surprise than current approaches to the method allow. I suggest that there is a risk of the pragmatic trial device becoming ‘old’ in the Rheinbergian sense, as in, reduced in its capacity to produce unexpected knowledge. Applying the logic of the pragmatic trial, with its tenets of standardization, fidelity, pre-determined outcome measures and the like, to the social world of ‘everyday practice’ may close down on the possibilities of encountering and explaining novel and unexpected findings and to account for the productivity of the method. There is a risk, essentially, of disallowing the experimental system to remain ‘young’ by enabling the encounter of the unexpected, through the over-prescription of the logics of the RCT to the experiment. The findings of this PhD suggest that including what would be considered ‘the surplus’, some of what is not in view under the current enactments of the pragmatic trial device and the RCT ontology may allow for this method to avoid the risk of becoming less relevant as paradigms shift and science takes on new meanings. In the quote below Rheinberger describes what can be seen as ‘the surplus’ of experiments:

‘discoveries’ – never happen in the way in which they become represented in the public arena, be it in research publications or in retrospective accounts of the actors. The historian of science who is lucky enough to have recourse to preserved laboratory notes can have the repeated experience that the order of the so-called discovery and the order of representation in science play in two different registers.... Techniques being applied can have results other than those intended, which means that such techniques create an excess that goes beyond the anticipated effect’ (Rheinberger, 2015: p.173).

Discussing one of Robert Merton’s proposed hallmarks of science, ‘specified ignorance’, Rheinberger suggests an alteration, ‘unspecified ignorance’. This, claims Rheinberger, is ‘ultimately what drives science’ (Rheinberger, 2015: p.170). In contrasting the pragmatic trial to the laboratory experiment, this point may come more clearly into view. Many laboratory experiments are oriented towards the encounter of ‘side effects’, for the unexpected impacts of a scientific provocation. Spacio-temporal factors and general containment may allow such effects to be in view in the laboratory setting, but move to the world of ‘everyday’ practice and the pragmatic trial and how might such ‘side effects’ be encountered? In this PhD, autoethnography, case study and process evaluation with their disciplinary and paradigmatic implications, have enabled a wider view of the productions of

the pragmatic trial experiment. An interdisciplinary, multi-method approach has enabled a challenging account of the trial to come into view.

I have described the logic of the pragmatic trial as attempting to account for the ‘social’ and the ‘scientific’, all the while understanding that these are false dichotomies. As this binary begins to dissolve in the face of evolving understandings of the interferences of the ‘social’ into even the hard sciences (See work by Latour, Haraway, Daston, Nowotny), bringing new understandings of the scientific into being, we are left with the likelihood that it is all ‘social’ and new ways of conceptualising these interactions are required.

Helga Nowotny, in her paper *‘Re-thinking Science: From Reliable Knowledge to Socially Robust Knowledge’*, describes an emerging era of science where society is beginning to ‘speak back’ to science, transforming what is understood to be the scientific and challenging long held scientific tenets such as objectivity and disinterestedness (Nowotny, 2000). She describes this point in the quote below:

‘The demarcations between science and non-science are no longer evident, whenever the ‘context of application’ merges seamlessly with the ‘context of implication’ that has been opened up. In this sense, the limits of science too are contested. Its autonomous space is no longer guaranteed, since its potential guardians, state, market and culture, are no longer recognisable there in their old identities, functions and roles....Our thesis is that a Mode 2 society generates the conditions in which society is able to ‘speak back’ to science; and that this reverse communication is transforming science.’ (Nowotny, 2000: p.3)

Mode 2 knowledge, described as ‘more open systems of knowledge production’ and the ‘growth of complexity in society’ (Nowotny, 2000: p.2), calls for a re-thinking of how scientific objectivity is understood, responding to the growing emphasis on context and the accelerating changes to both science and society as understood contemporarily. Nowotny describes an ‘objectivity trap’ where as researchers we need to demonstrate how contextualised knowledge can be as rigorous as traditionally ‘disinterested’ knowledge (Nowotny 2000: p.6). What she suggests is ‘socially robust’ knowledge production, where the scientific community works at ‘acknowledging that objective knowledge is the result of a



historical process, which inevitably renders it partial and contextual’ and places emphasis on the ‘specific locations, instances and conditions in which it is produced, applied, contested or negotiated’ (Nowotny, 2000: p.10). This contrasting conceptualisation of reliability would transform understandings of science and better incorporate this entrance of ‘the social’.

The pragmatic trial can be seen within the trajectory outlined by Nowotny. Some of what has been proposed here within is the continued consideration of what socially robust knowledge might look like in the practice of methods such as trials. Instead of a continued attempt to ‘hammer down’ on the social and transform context into science style facts that can be easily measured and accounted for, I suggest allowing experimental devices to remain open and allowing the methodological apparatuses and bureaucracies they carry in their train to transform in the space of these new considerations.

What has been described above and considered throughout the thesis is the contemporary challenges the entrance of ‘context’ and ‘the social’ has had on the logics of science, evaluation and evidence. This aligns with what Nowotny proposes and would benefit from her propositions. The determination of evidence, production of knowledge, and articulation of validity, for example, may be altered in the face of a dissolving bifurcation between the scientific and the social. How to keep the pragmatic trial ‘young’ in the Rheinbergian sense, as able to generate novel new insight, may benefit from such considerations, as would what it means to be a diseased body that is living well. Mode 2, socially robust knowledge may be better able to account for contingency, emergence, speculation, uncertainty and multiplicity and consider these phenomena not as affronts to science in need of traditional containment but as what may help qualify new understandings.

### **13.6 Recommendations for further research**

*The DOI model as a prospective trial design tool*

The diffusion of innovations for health care organisations model by Greenhalgh et al. (2004)

proved a useful theoretical frame for exploring the variation in rapid HIV testing uptake retrospectively. I also believe the model holds potential to be used prospectively. In visiting the intervention practices in RHIVA2 prior to the start of the trial many of the aspects present in the Greenhalgh et al. model could have been considered. It was obvious from an early stage that some practices appeared more open and ready for testing than others, yet I lacked a framework through which to consider, evaluate and comment on this. Using the model prospectively would have enabled conversations among the trial team and with the practices regarding areas of potential strength and weakness in delivering the intervention and participating in the trial.

As RHIVA2 aimed to implement and evaluate simultaneously, the trial team was not tasked with solely measuring the impact of a new innovation but also delivering it and so implementation pathways were of consideration all the way through. This raises the question of whether an intervention with a theorised implementation process which accounted for contextual factors would have been appropriate alongside a design which aims to measure ‘everyday’ practice, since it would then be seeking to measure both the implementation process and the ‘business as usual’ of everyday practice. Despite this, a theoretical frame that complex interventions can be considered against, at the research design stage, may allow for a greater understanding of interventions and aspects impacting their implementation.

### *Situated protocols and re-oriented fidelity*

Pragmatic clinical trials are meant to account for the contextual factors implicated in the ‘real-life’ setting of the clinic (Tosh et al., 2013; Kelly, 2008). General practices are diverse; each with their own set of contextual factors and established routines. What became apparent throughout the trial and in applying the diffusion of innovations in health care settings model to the practice-level data was the potential utility of allowing – even promoting – flexibility in the way practices implement the intervention whilst retaining its fidelity with the aims of the research program versus as an overly standardised set of practices and pathways across diverse settings. As discussed by Hawe and Shiell, ‘fidelity defined functionally rather than compositionally’ may be key (Hawe and Shiell, 2004: p. 1563).

This approach may allow interventions to be meaningfully evaluated while still being responsive to their context and respectful of existing practices in the implementation setting (McMullen et al., 2015). This may mean working with intervention sites to develop site-specific protocols which retain fidelity and the relative standardisation of the intervention required by trial principles, while reflecting how the intervention would actually be rolled out in practice (McMullen et al., 2015). This suggestion reflects on the understanding that as an intervention is implemented as a part of research it brings forth its own set of apparatuses and bureaucratic processes that impact how an intervention can be implemented.

### *Trial co-design*

Co-design has been an area of rising practical and academic curiosity and evaluation (Bate and Robert, 2006). Here, patients and providers are involved in the identification, implementation and gradual improvement of health care services with emphasis on their experience of services their placement at the centre of service design (Bate and Robert, 2006). This aims to move the emphasis away from management processes and emphasizes the design of ‘experiences rather than processes’ (Bate and Robert, 2006: 308). This thesis has demonstrated the important role patients and providers play in making research designs and new innovations functional and productive, including in unexpected ways. While the piloting of research designs along with feasibility and acceptability studies have traditionally been the standard process of testing user acceptability and of attuning designs to their context, the more explicit involvement of patients and providers in the design and conduct of trials, using models such as patient co-design may open exciting possibilities for more socially accountable trials which better respond to patient needs and preferences with potentially more sustained impacts. As explored in Chapter 11, patient subjectivities are one way in which trial findings are generated ‘bit by bit’. The emphasis of the emerging approach of co-design for services is relevant to events such as RHIVA2 where new innovations are being implemented and evaluated simultaneously. Co-design of trial algorithms may have revealed health care provider concerns around sharing reactive results and may have highlighted the issue of interpretation and interpreted consultations at the design stage as a potentially important aspect of the intervention. The logic of normalisation, with its paradoxical patterning of patient preferences was revealed through an

emphasis on patient experience. Trials such as RHIVA2 could benefit from a co-design approach where ‘the traditional view of the user as a passive recipient of a product or service gives way to the new view of users as the co-designers of that product or service, and integral to the improvement and innovation process’ (Bate and Robert, 2006: p.308).

### **13.7 Conclusion: Maintaining space**

‘The critique of simplification is so well established it has become a morally comfortable place to be (...) the endless mobilizations of this single trope, in which simplification figures as a reduction of complexity, leaves a great deal to discover and articulate. We need other ways of relating to complexity, other ways for complexity to be accepted, produced, or performed.’ (Law and Mol, 2002: p.5)

A point of alignment between what many of the theorists introduced in the thesis suggest and what has been presented in the findings of this thesis is the importance of a form of ‘space’. For example, in Viveiros de Castro’s concept of controlled equivocation he describes the space for divergence and meaning to equivocate and be productively interpreted (Viveiros de Castro, 2004). Annemarie Mol’s multiple ontology of disease, describes how multiple realities take hold around a disease concept (Mol, 2002). In the pragmatic trial, key is space for the ‘real world’ to enter and act (Kelly, 2008). And in the experiment, space for the unexpected to be perceived and to occur is described by Rheinberger, as the driving force of science (Rheinberger, 2015). ‘Space’ for response and a lack of uniformity appear key for productive inquiry. The RHIVA2 trial was effective because of enacted pragmatism on the part of patients and providers and their responsiveness to emerging, unpredictable situations. However, the pragmatic trial design as operationalised in RHIVA2 was somewhat unable to articulate this pragmatism, as demonstrated in Chapter 12. Patients were able to have divergent, subjective questions answered through the rapid HIV test as shown in Chapter 11. Multiple HIV’s were mobilized to justify the original policy tested in RHIVA2 as described in Part 1.

**Perhaps the overarching recommendation about applied research to emerge from this PhD is to be cautious about the will to overly specify, standardise, and hammer down on phenomena through constrictive practices.** Allowing for multiplicity, pragmatic practices, equivocations and onwards may allow for better care, science and research. A willingness to

engage with uncertainty, the surplus and the responsiveness of phenomena to experimental probes through an interdisciplinary engagement with methods, theory and the findings is how the RHIVA2 trial and the work of this PhD became meaningful to me. In my view this was how most original and productive insights and findings described herein were produced.

## 14. REFERENCES

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## 15. Appendices

### Appendix 1: Interview schedule for provider interviews

#### Semi Structured Provider Interview Guide

QUESTION	Coding Theme – DOI Model	RESPONSE
1. What are your thoughts about providing rapid HIV Testing in Primary Care?	A.2 Compatibility H.1- Tension for Change H.2 – Innovation System Fit	
2. What do you think the impact of testing in primary care is?	H.4- Assessment of Implications H.2 Innovation System Fit G.3 Values and Goals	
3. HIV is often dealt with within specialist services. What do you think about providing a service commonly provided in specialist settings in general practice?	H.4- Assessment of Implications H.2 Innovation System Fit A.2 Compatibility G.3 Values and Goals	
4. How does a new GP surgery need to be equipped to deal with a new HIV diagnosis? What does a surgery need?	H.5 – Dedicated time and resources G.4 Skills	
5. Do you think that other sexual health services should be prioritised in the same way?	C.2 Incentives and mandates I.2 Absorptive capacity for new knowledge	
6. When did you offer the INSTI test within the new patient health check?	A.2 – Compatibility A.5 – Potential for reinvention F.2- Soft periphery elements	

	H.5 – Dedicated time and resources	
7. How long do you think it takes? Did you find that you got faster with time and practice using the test?	A.2 – Compatibility A.5 – Potential for reinvention F.2- Soft periphery elements H.5 – Dedicated time and resources	
8. Did you enjoy / dislike providing the test to patients?	G.1 – Needs G.2- Motivation G.3 – Values and Goals A.2 – Compatibility A.3 – Low complexity A.1 – Relative Advantage	
9. Did you offer the test in other consultations? Which ones?	F.1- Soft periphery elements A.5- Potential for reinvention	
10. Where there areas where you thought the INSTI should be offered but was not?	G.2- Motivation G.5 – Values and goals	
11. Did you have a lot of declines? In your opinion were there groups that refused the test more than others? Did you ever try to convince a patient to have the INSTI? Why do you think people declined? What reasons did they give you?	A.1- Relative advantage G.4- Skills	
12. Is there anyone that you did not offer the test to who was within the inclusion criteria? Why?	A.5- Potential for reinvention E.7- Reinvention/Development	

13. How did you manage instances of accompanied patients?	A.5- Potential for reinvention E.7- Reinvention/Development G.2- Motivation H.2 – Innovation-system Fit H.4- Assessment of implications	
14. Did any patient ever come and ask you specifically for the INSTI test because they had heard of it?		
15. Did you find the test easy to use?	A.2- Compatibility A.3- Low complexity A.8- Nature of Knowledge A.9- Technical support	
16. Was there any practical aspects of the test that you found difficult?	A.2- Compatibility A.3- Low complexity A.8- Nature of Knowledge A.9- Technical support E.3.- Human resource issues (training)	
17. Were there any instances where you struggled to interpret the results?	A.2- Compatibility A.3- Low complexity A.8- Nature of Knowledge A.9- Technical support E.3.- Human resource issues (training)	
18. Do you have any ideas or recommendations of how to make the test itself easier to use?	A.2- Compatibility A.3- Low complexity A.8- Nature of Knowledge A.9- Technical support G.1- Needs	

19. Did you ever have a reactive, invalid or indeterminate result?		
20. How did you deal with sharing the results?	G.4- Skills 1.3.i – Good managerial relations	
21. How was the insertion of the test result into EMIS?	A.1- Complexity A.2 – Compatibility A.9- Technical support I.3.v- High quality data capture	
22. What kind of questions did patients ask you about the HIV including HIV testing? What kind of comments did you receive from the patients about offering the rapid test in the NPHC?	A.8 – Nature of knowledge A.2- Compatibility	
23. Did you find that offering the HIV testing changed the nature of the consultation?	A.2- Compatibility G.3- Values and Goals	
24. How comfortable did you feel offering the test?	G.3- Values and goals G.2 – Motivation A.8- Nature of knowledge E.3.- Human resource issues (training)	
25. Were you worried about how you would deal with a reactive result?	A.7 – Task issues A.8 – Nature of knowledge G.4- Skills A.2- Compatibility	
26. Do you feel that you have the right skills to be able to share a reactive result with a patient?	A.7 – Task issues A.8 – Nature of knowledge G.4- Skills	



	A.2- Compatibility	
27. Did you find that patients were open to the testing?	A.2 – Compatibility A.1 – Relative Advantage	
29. How did patients react to their results?	I.3.iii	
30. In the instances of reactive, indeterminate or invalid results how were the patient reactions?	A.2- Compatibility I.3.iii	
31. Did patients ask about offering the test, or getting the test for people they know?		
32. Did you encounter any negative or positive reactions to offering the test?	I.3.iii	
33. Did you find you had enough time to be able to deal with patient questions etc?	I.1.v.- Slack Resources H.5- Dedicated time and resources A.8- Nature of knowledge	
34. How did you find the GP Education Sessions? Did you feel that you had sufficient training?	E.3 – Human resource issues (training)	
35. Where you ever lost for what to do?	A.8- Nature of knowledge H.4- Skills I.3.i – Leadership and vision I.3.ii- Good Managerial relations E.2- Hands-on approach by leaders and managers	
36. Were there any instances where you struggled with interpreting test results of	A.8- Nature of knowledge H.4- Skills	

actual patients?	E.3.- Human resource issues (training)	
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## **Appendix 2: The Diffusion of Innovations Coding Frame**

### **The Diffusion of Innovations Coding Frame**

#### **A) The Innovation**

- 1) Relative Advantage
- 2) Compatibility
- 3) Low complexity
- 4) Observability
- 5) Potential for Reinvention
- 6) Fuzzy Boundaries
- 7) Task Issues
- 8) Nature of Knowledge
- 9) Technical Support

#### **B) Communication and Influence**

- 1) Social Networks
- 2) Homophily
- 3) Peer Opinion
- 4) Marketing
- 5) Expert Opinion
- 6) Champions
- 7) Boundary Spanners
- 8) Change Agents

#### **C) Outer Context**

- 1) Socio-political Climate
- 2) Incentives and Mandates
- 3) Inter-organisational norm setting and networks
- 4) Environmental stability

#### **D) Linkage**

##### *Design Stage*

- 1) Shared Meanings and Mission
- 2) Effective Knowledge Transfer
- 3) User Involvement in Specification
- 4) Capture of User Led Innovation

##### *Implementation Stage*

- 5) Communication and Information
- 6) User Orientation
- 7) Product Augmentation (technical help)
- 8) Project Management and Support

#### **E) Implementation Process**

- 1) Decision making devolved to frontline teams
- 2) Hands-on approach by leaders and managers

- 3) Human resource issues, especially training
- 4) Dedicated resources
- 5) Internal communication
- 6) External collaboration
- 7) Reinvention/Development
- 8) Feedback on progress

**F) Assimilation**

- 1) Complex, nonlinear process
- 2) 'Soft Periphery' elements

**G) Adopter**

- 1) Needs
- 2) Motivation
- 3) Values and Goals
- 4) Skills
- 5) Learning Style
- 6) Social Networks

**H) System Readiness for Innovation**

- 1) Tension for Change
- 2) Innovation-system Fit
- 3) Power Balances (supports vs. opponents)
- 4) Assessment of Implications
- 5) Dedicated time and resources
- 6) Monitoring and Feedback

**I) System Antecedents for Change**

- 1) Structure
  - i. Size/Maturity
  - ii. Formalisation
  - iii. Differentiation
  - iv. Decentralisation
  - v. Slack Resources
- 2) Absorptive Capacity for new knowledge
  - i. Pre-existing knowledge/skills base
  - ii. Ability to find, interpret, re-codify and integrate new knowledge
  - iii. Enablement of knowledge sharing
- 3) Receptive Context for Change
  - i. Leadership and Vision
  - ii. Good managerial relations
  - iii. Risk – taking climate
  - iv. Clear goals and priorities
  - v. High Quality data captur

### Appendix 3: Example of qualitative charting

RHIVA Qualitative Coding for DoI Model		
nt. Number	Quote	Code
k	<p>Interviewer: What do you think a surgery needs to be able to deal with offering the testing in this way do you think more training...</p> <p>Respondent: Time.</p> <p>Interviewer: ... more time?</p> <p>Respondent: It's time.</p>	A)8. Risk E)4. Dedicated Resources
k	<p>Respondent: And the thing is that often I have to do like a just a quick health check, blood pressure, weight, all that, at the same time. And that's all got to be squeezed in to 15 minutes. And the patient's got to get undressed, dressed.</p> <p>Interviewer: Yeah. Definitely.</p> <p>Respondent: And especially at the moment with the cold weather everybody's got a hundred layers on.</p> <p>Interviewer: That's true. So how long do you think it takes to do the INSTI?</p> <p>Respondent: Five minutes.</p> <p>Interviewer: Yeah.</p> <p>Respondent: It's really not long at all. It's more the chatting than the actual doing of.</p> <p>Respondent: It really is not a problem. It's just, you know, having the time. I mean often I get to the end of a morning and I feel like a rag.</p>	A)8. Risk E)4. Dedicated Resources <i>How to code 'feel like a rag'</i>
k	<p>Interviewer: Yeah. Do you like doing the testing?</p> <p>Respondent: Actually, yes, I do.</p> <p>Interviewer: What do you like about it?</p> <p>Respondent: I like the fact that people are so impressed by it.</p> <p>Interviewer: By how fast it is?</p> <p>Respondent: Not just that, it's the fact that they get an instant result. And if they're worried about it then that's very gratifying for both me and them.</p>	Patient ToM A)1. Relative Advantage G)2. Motivation
k	<p>Respondent: I don't have any difficulty with it at all actually. As long as I get a decent drop of blood, just occasionally people don't bleed terribly well. I don't like the finger-pricker they give with it. I tend to use my ones.</p> <p>Interviewer: Okay.</p> <p>Respondent: These ones.</p> <p>Interviewer: Yeah.</p> <p>Respondent: They're a bit more gentle.</p>	Patient ToM G)3. Values? (gentle) A)6. Potential for Reinvention A)3 Complexity?/tech aspect or risk? Stigma? Believing

#### **Appendix 4: Examples of field notes.**

Please see the following examples of field notes. Names and details have been anonymised.

##### **Example 1: Primary Issues with Testing**

Daswani practice was trained and supplied with all necessary equipment to start testing on June 8<sup>th</sup>, 2010. The first round of quality assurance activities was delivered on July 10<sup>th</sup>, 2010. Daswani practice never returned their quality assurance information to the lab, scoring 0 on the assessment. On the 11<sup>th</sup> I received a phone call from a practice nurse at the Oak practice which shares the X Road Medical Centre. Both practices were trained at the same time as they are both small practices in the same building. Later on in the trial Reyah also took on one morning a week at the Oak practice in addition to her work at Daswani practice. The nurse from Oak practice wanted to inform me that when the quality assurance arrived, Reyah had asked her for some test kits as she didn't have any. Daswani was supplied with 100 test kits at the training. These were placed in the clinical supplies cupboard along with other clinical materials. It seems that Reyah did not know where the supplies were being kept. I asked CEG to pull up their EMIS testing numbers and it indicated that all tests offered were declined. Reyah had a 100% decline rate in the first year of testing. She offered 33 tests, which were all turned down. There is some reason to believe that they were never offered as at least in the beginning she did not have any test kits but was registering results. Other low levels of test acceptance in the trial are mostly due to rearrangements of the new patient health check, meaning that patients are offered the test on a checklist or need to attend an additional appointment to have it. Even in these scenarios we never saw decline rates nearing 100%. When offered usually between 35 and 70% of patients will agree to the test. After learning of the unknown test kits and the declined entries I raised the issue with the team worried that she was falsifying data. I was told not to frustrate the practice or they would refuse to participate altogether. I sent the below email to Reyah and asked to visit the practice to see if any retraining was needed.

*Dear x,*

*The message was passed along to me that you were unable to find the INSTI test kits required to perform the External Quality Assurance Protocol. As I recall, x has stored them in the storage cupboard in a large box. They were one of the first boxes upon entry.*

*I suppose this means that you have not started testing at the surgery? Please let me know what you may require in terms of support to get started. The surgery is being paid ten pounds per test performed.*

*Thank You and Best Wishes*

## **Example 2: RHIVA Power Calculations**

Friday 11/03/2011 15:55

Hi X,X,X,

When you get to the stage in the minutes where you define the new power calculations and what data is required you can pass it along so that I can document.

Does this qualify as an adverse event? How am I meant to reflect these changes in the TMF?

Also, it was suggested I come up with another time for a meeting next month.

I am guessing we will need these done before then. What kind of time frame am I looking at? I want to give people enough notice so that they might actually be able to attend a whole meeting, but also make sure we will have what we need by then.

Thanks,

Heather McMullen RHIVA Manager

### **Example 3: Safiye – HCA and Practice Rapid Testing Lead**

Safiye is a large bubbly woman with a strong East London accent, young and energetic she is easy to talk to and unpretentious in her manner. Her family is Middle Eastern but she is East London raised. A recent mom, she will quickly begin telling you all about her struggles to manage work and being a single parent. All her anecdotes contain humour, she often pokes fun at herself and any story is peppered with check in comments for her audience such as, ‘oh my god, can you imagine’ ‘could you believe it’ etc. She is very sincere in her interactions and is warm in her approach. I imagine patients would feel very comfortable speaking with her about their various concerns. When asking about rapid testing I find that she will reply in ways that seem genuine, taking responsibility for things she could have done better and replying with answers that one might not be quick to share with most researchers.

Safiye believes rapid testing in general practice is a good idea and expresses ‘100%’ support, she also shows great compassion towards patients demonstrating much concern for their feelings and experiences.

Safiye spoke a lot about the fear of having a positive result however she mentioned on more than one occasion how keen she was to see one.

Safiye valorises the emotional aspects of testing. She speaks a lot about feelings and experiencing feelings. In regards to apprehensions about testing her biggest concern was upsetting a patient with a potentially false result. This example also demonstrates a lack of understanding of test kit in that insufficient blood would not give a false negative but an invalid result.

Safiye was really keen to be helpful. She gave me her personal phone numbers, encouraging me to call her on her mobile instead of through the surgery as that would mean that I could get through faster with any queries. She seemed proud to be the practice lead on rapid testing. On the occasion where I was actively trying to reach her to confirm training and chase up a confusing result from EMIS I was unable to do so with any of the means provided. It usually took many attempts and unreturned messages before I could reach her. I took to popping into the surgery when I was in the area if there was anything outstanding. It was often more convenient for me to stop in and try and speak to someone in person rather than get involved in phone tag.

She was quick to take responsibility for her role in the trial when I interviewed her. In the initial meeting I set up to ask about the lack of testing at the practice and to troubleshoot we identified there was a problem with the distribution of the Patient Information Sheets, a requirement of ethics. All patients are meant to have received and reviewed a double sided patient information sheet explaining that they will be offered a rapid HIV test. Safiye was always quite concerned with ensuring patients understood that testing was part of a research project. It took a few months to get this adequately sorted out with reception and to ensure



that the Patient Information Sheets were being attached in the new registrants pack. Safiye was not performing the test on anyone who had not received the information sheet and articulated this as the reason for a lack of testing. I found this interesting in that if all practices had been so pedantic about having evidence of patients viewing the patient information sheet I am sure we would have had less tests performed. From the first training we anticipated this may be an issue and I had copies of the PIS printed in 8 languages, in different colours, and laminated so that a copy could be kept in the consultation room. It was advised that if patients had not seen the information sheet they could view it then and agree.

It turned out this approach was counter to the ethical stipulations. Patients were meant to see the patient information sheet 24 hours prior to being offered the test. Normally this is not an issue as most patients wait some time between registering and their NPHC. However, Practice X forced us to look more carefully at this ethical stipulation as they often offer both registration and the NPHC in the same day. A further consideration of the ethical requirement made us realise it was barrier to testing. We also thought that the requirements exceptionalised HIV testing. When discussing with various team members the requirement caused significant frustrations, particularly with the HIV liaison nurse who often comes up against the exceptionalising of HIV testing in hospital. She has many anecdotes of patients who do not speak English yet have had x-rays, urine tests, some blood tests in the hospital setting yet need a patient advocate and consent form for an HIV test. As we were unable to see precedence in primary care for this wait period and saw it as a relic of the past implications of being HIV positive we applied for an amendment. As patients were to be offered the test during the new patient health check but were unable to be offered if they had not had a 24 hour consideration period, patients of surgeries who performed same day registration and health check were missing out on the opportunity to be tested. This was also skewing the numbers for our trial as these patients met the inclusion criteria and were undergoing NPHC. The amendment was accepted.

It was interesting to see how surgery registration routines could exclude some patients from the opportunity to test. None of the other surgeries reported this issue. Practice X was somewhat unique in the borough in its organisation of the NPHC. Another surgery had a somewhat similar approach however their NPHC was condensed to the point that it was performed by the receptionist at the point of registration. A scale, height measure and blood pressure machine are set beside the registration desk. The patient fills out a questionnaire and proceeds to do their height, weight and BP in plain sight of the waiting room. When speaking to various receptionists across the borough about how the NPHC evolved to this point many cited the removal of the NPHC payment and the payment per registrants a major incentive. They were keen to register people quickly but could not afford the resources required for long NPHC. This is another aspect that makes Practice Y so unique, there is 30 minutes afforded to each NPCH. The norm is 10-15. I believe this to be strongly related to the test acceptance rate and overall good performance of Practice X.

#### **Example 4: Reactive result algorithms**

**From:** Heather McMullen

**Sent:** 16 August 2010 16:48

**To:** X

**Cc:** X

**Subject:** Marking of the EQAs and New Reactive

Hi X and X,

See X response regarding EQAs below and action to be taken regarding serum quantity.

As for X (X- August 4<sup>th</sup>) reactive result, as mentioned by X, it seems that she followed the algorithm well and referred to the GP but that the GP sent the patient to X for bloodwork / venous blood confirmatory testing, and did not contact X or follow up. At the moment it appears the patient never showed up to X for bloodwork. X is now on the case and I am expecting an update from her.

I had a very productive meeting with X this afternoon (where I learned about the reactive result) and she is feeling better about testing and performing EQAs.

I am a bit concerned that we may not know about a few other 'abnormal' results and since we cannot yet access records via EMIS I am planning a check in with all lead nurses this week for an update as to how things have been progressing in the surgeries, this will also provide me with an opportunity to see how they are managing to distribute patient information sheets.

X when would you like to meet this week? I am not in Wednesday.

Thanks, Heather

## Appendix 5: Example of information and consent form

### **RHIVA 2: Health Provider and Patient experiences and Perspectives on Rapid HIV Testing in Primary Care: A Qualitative Study**

### **Policy Maker Participant Information and Consent Form**

**Title of study:**

RHIVA 2: Health Provider and Patient experiences and Perspectives on Rapid HIV Testing in Primary Care: A Qualitative Study

**Researcher:** Heather McMullen

**Institute:** Centre for Primary Care and Public Health, Barts and The London School of Medicine and Dentistry, Queen Mary University of London (QMUL)

#### **1.1 What is the purpose of the study?**

RHIVA 2 is a trial of rapid HIV testing in Primary Care that is being rolled out in participating Hackney General Practices. The main objective is to demonstrate that rapid HIV testing, if integrated into the GP registration health check, increases the rate of HIV testing and detects cases at an earlier stage in the infection.

In addition to the testing trial we want to do some qualitative research to help us understand the feasibility and acceptability of providing testing in this way. We feel that provider perspectives and experiences are important in determining this. We also feel that understanding the policy decisions that led to the development of rapid HIV testing help us to understand how national policies translate into patient and provider experiences.

#### **1.2 Why have I been invited?**

You have been invited to participate in this study due to your involvement in the development and implementation of HIV testing policy in the United Kingdom.

#### **1.3 What will happen to me if I take part?**

It is up to you to decide to join the study. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You will be consenting to be interviewed about your involvement in national HIV policy. You are free to withdraw at any time, without giving a reason. This will not affect your employment. You may also refuse to answer any of the questions asked or end the interview at any point. If after the interview you decide you no longer want to participate we will withdraw you from the study.

#### **1.4 What will I have to do?**

We will be doing semi-structured interviews which means we have a number of themes we want to explore and will ask a number of questions to help us do this. We estimate the interview to take between 45 minutes to 1 hour. You will only be interviewed once. We will find a quiet space to conduct the interview.

We ask similar questions to all participants. You can refuse to answer any question but we do ask that when you answer you answer honestly. The information you provide will be presented in an anonymous way. When we have completed the study we will share the findings with you.

**1.6 What are the possible disadvantages and risks of taking part?**

There are no apparent risks involved in this study. We do ask you for some of your time. It may be that you discuss sensitive matters with us although what you share in the interview is up to you.

**1.7 What are the possible benefits of taking part?**

The benefits include helping us better understand the impacts of providing rapid HIV testing in primary care. We cannot promise the study will help you but the information we get from this study will help improve HIV services and care.

**1.8 What happens when the research study stops?**

If the research study stops you will be notified. The data we have collected will be dealt with in accordance with QMUL data management procedures.

**1.9 What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions on 0207 7882 7084 Please ask for Heather McMullen of the RHIVA 2 Trial.

**2. Will my taking part in the study be kept confidential?**

The information provided by you will remain confidential. Nobody except the research team will have access to it. All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you will have your name and address removed so that you cannot be recognized. We will do this by replacing your name with a code.

If the data is written up for publication in a journal or other research related material what you have shared with us will be presented anonymously. It may be that we include some quotations in the final write up. These will be presented anonymously. All data will be handled in line with QMUL data management guidelines to protect confidentiality and security.

**2.1 What will happen if I don't want to carry on with the study?**

If at any point during the interview you want to stop that is absolutely fine. We will stop the interview and the recording and the information will not be used in the study. If at any point after the interview and before writing up the research you feel that you would like to withdraw your participation contact the research team and we will withdraw you from the study.

**2.2 What will happen to the results of the research study?**

The results of the study will be published as academic research and used to inform policy around HIV testing. It is possible that some direct quotations from our interview will be used. They will however be presented in an anonymised way which means you will not be identified as the person who said it.

**2.3 Who is organising and funding the research?**

The study is being organised by QMUL. The research is being funded by NHS City & Hackney and the Department of Health. We are also working closely with Homerton Hospital and University College London.

**2.4 Who has reviewed the study?**

The study has been reviewed by the Central London Research Ethics Committee 2.

**2.5 Further information and contact details?**

If you have any further questions you may contact Heather McMullen, researcher at QMUL: [h.mcmullen@qmul.ac.uk](mailto:h.mcmullen@qmul.ac.uk) – 0207 882 7084.

**RHIVA 2 Trial: Health Provider and Patient experiences and Perspectives on Rapid HIV Testing in Primary Care: A Qualitative Study – Policy Level Study**

**Centre Number:**  
**Study Number:**  
**Provider Identification Number:**  
**Name of Researcher:**

**Written Informed Consent Form**

I confirm that I have read and understood the information sheet dated RHIVA2QualiPolicyLevelStudyInfoSheetConsentForm\_Sept32013 for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.

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.

I confirm that I understand that my interview will be used as data within the RHIVA 2 research but that when presented for publication it will be done so anonymously. It may include quotations from the interview but they will be presented anonymously.

I have read and understand this consent form, and I volunteer to participate in this research study.

I agree to be contacted in the future to share study results or follow up the research.

**Participant's Name:**  
**Date:**  
**Participant's Signature:**  
**Date:**

**Name of Person Obtaining Consent:**  
**Signature of Person Obtaining Consent:**  
**Date:**

**Name of Witness if required:**  
**Signature of Witness (if required):**  
**Date:**

## Appendix 6: Published paper in Trials

McMullen et al. *Trials* (2015) 16:242  
DOI 10.1186/s13063-015-0755-5



RESEARCH

Open Access



# Explaining high and low performers in complex intervention trials: a new model based on diffusion of innovations theory

Heather McMullen<sup>1\*</sup>, Chris Griffiths<sup>1</sup>, Werner Leber<sup>1</sup> and Trisha Greenhalgh<sup>2</sup>

### Abstract

**Background:** Complex intervention trials may require health care organisations to implement new service models. In a recent cluster randomised controlled trial, some participating organisations achieved high recruitment, whereas others found it difficult to assimilate the intervention and were low recruiters. We sought to explain this variation and develop a model to inform organisational participation in future complex intervention trials.

**Methods:** The trial included 40 general practices in a London borough with high HIV prevalence. The intervention was offering a rapid HIV test as part of the New Patient Health Check. The primary outcome was mean CD4 cell count at diagnosis. The process evaluation consisted of several hundred hours of ethnographic observation, 21 semi-structured interviews and analysis of routine documents (e.g., patient leaflets, clinical protocols) and trial documents (e.g., inclusion criteria, recruitment statistics). Qualitative data were analysed thematically using—and, where necessary, extending—Greenhalgh et al.'s model of diffusion of innovations. Narrative synthesis was used to prepare case studies of four practices representing maximum variety in clinicians' interest in HIV (assessed by level of serological testing prior to the trial) and performance in the trial (high vs. low recruiters).

**Results:** High-recruiting practices were, in general though not invariably, also innovative practices. They were characterised by strong leadership, good managerial relations, readiness for change, a culture of staff training and available staff time ('slack resources'). Their front-line staff believed that patients might benefit from the rapid HIV test ('relative advantage'), were emotionally comfortable administering it ('compatibility'), skilled in performing it ('task issues') and made creative adaptations to embed the test in local working practices ('reinvention'). Early experience of a positive HIV test ('observability') appeared to reinforce staff commitment to recruiting more participants. Low-performing practices typically had less good managerial relations, significant resource constraints, staff discomfort with the test and no positive results early in the trial.

**Conclusions:** An adaptation of the diffusion of innovations model was an effective analytical tool for retrospectively explaining high and low-performing practices in a complex intervention research trial. Whether the model will work prospectively to predict performance (and hence shape the design of future trials) is unknown.

**Trial registration:** ISRCTN Registry number: ISRCTN63473710. Date assigned: 22 April 2010.

**Keywords:** Complex interventions, Diffusion of innovations, Point of care testing

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## Background

### Introduction

A *complex intervention* is defined by the Medical Research Council (MRC) as comprising multiple elements, all of which seem essential but whose 'active ingredient' may be difficult to specify; they typically operate at multiple levels (individual, team, organisation) [1–3]. Such interventions include new tests and treatments that create opportunities for changing how services are delivered (e.g., near-patient testing that potentially allows diagnoses to be made in primary care that were previously possible only in secondary care).

Much health services research consists of developing complex interventions and testing them in randomised controlled trials (RCTs). The MRC framework proposes five phases (0 to 4), including developmental and pilot work, the trial itself and an evaluation of post-trial implementation in the 'real world' [4]. Complex intervention trials generally require a cluster design (in which the organisation or service team is the unit of randomisation) and are studied through a pragmatic lens (i.e., seeking to replicate usual care as delivered by the staff and through systems in participating organisations) rather than an explanatory one (i.e., seeking to produce abstracted theoretical models of efficacy with an emphasis on scientific purity) [5, 6].

A growing theoretical and methodological literature addresses the question whether interventions that are *complex* can legitimately be tested using experimental designs in which they are conceptualised as a clearly defined set of inputs implemented in a controlled way with attention to mediating and moderating variables [4, 7, 8] or whether their complexity requires a more ecological conceptualisation as 'events in systems' and (therefore) developmental rather than experimental research designs [9–12]. Either way, a key focus of study is the interaction between the complex intervention and the local settings in which it is implemented [3, 13, 14].

An important concept is the idea of a theoretical 'hard core' of a complex intervention (elements that cannot be compromised without invalidating the trial) and a flexible 'soft periphery' (elements of the intervention that can and should be adapted locally to optimise acceptance and embedding) [15, 16]. In any complex intervention trial, each unit (e.g., participating organisation or team) will implement the intervention differently, so a component of trial quality is ensuring fidelity of the theoretical core [2, 15].

The emerging science of process evaluation uses qualitative research alongside a RCT to capture the experiences of staff and patients, illuminate tasks and processes, explore model–reality gaps and develop and test theory [17, 18]. Such approaches can be used both retrospectively (to explain successes and failures) and prospectively (to inform further refinement of the intervention). Specific

theoretical lenses applied in this context include normalisation process theory [19] and realist evaluation [20], though the latter has been contested [21].

One approach that has not previously been used to study the process of implementing a complex intervention in a RCT is diffusion of innovations theory. Originally developed by Everett Rogers in the 1950s to explain the adoption and spread of innovations by individuals in a social network [22], the theory was later extended by Greenhalgh et al. to address the assimilation and implementation of service-level innovations in health care organisations [23]. Greenhalgh et al.'s definition of an innovation as "a novel set of behaviors, routines, and ways of working that are directed at improving health outcomes, administrative efficiency, cost effectiveness, or users' experience and that are implemented by planned and coordinated actions" ([23], p. 582) agrees strongly with the MRC definition of a complex intervention (paragraph 1). It follows that the multi-level model developed by Greenhalgh et al. to study the adoption (and non-adoption and abandonment) of innovations may also prove useful for explaining variation in implementation success in complex intervention trials.

In this article, we apply Greenhalgh et al.'s model to a retrospective process evaluation of a complex intervention to introduce rapid HIV testing in a general practice setting. Below we summarise the trial and introduce the diffusion of innovations model and then describe our methodology, findings and conclusions. In the Discussion section, we offer preliminary suggestions for using the diffusion of innovations model prospectively to optimise organisational participation in trials.

### The trial of rapid HIV testing in general practice

A summary of the rationale, methodology and findings of this trial have been published elsewhere [24, 25]. Briefly, general practice–based screening for HIV is appealing, given the rising prevalence of the condition in the United Kingdom (especially London), a good prognosis if treated early, the high proportion of cases (24 %) that remain undiagnosed in the community and the high proportion (47 %) of patients diagnosed with advanced disease [26]. The British HIV Association and the National Institute for Health and Care Excellence both support community-based testing in areas where the prevalence of diagnosed HIV is above 2 per 1000 adult population [27, 28], but such testing has not previously been evaluated experimentally in real-world conditions.

Rapid (near-patient) testing provides an accessible means of testing large numbers of people in non-specialist settings. We used the INSTI™ HIV-1/HIV-2 Rapid Antibody Test (bioLytical Laboratories, Richmond, BC, Canada), which is quick to learn and easy to use and thus potentially able to be used by staff with minimal training (see Box 1). The INSTI test has a high sensitivity of



**Box 1** The intervention: rapid HIV testing in general practice

The 'hard core' of the intervention [16] was the INSTI HIV-1/HIV-2 Rapid Antibody Test (bioLytical Laboratories, Richmond, BC, Canada). The single-use test involves 50 µl of finger-prick blood, which was mixed with a sample diluent and poured onto a membrane unit, followed by a drop of developer and clarifying solution. After about 1 min, either one or two blue dots would appear, indicating one of four possible results: non-reactive (one blue dot, negative), reactive (two blue dots, suggesting the presence of HIV antibody in patient serum), indeterminate (e.g., two faint dots or two dots with one displaying a pale centre, suggesting possible early infection) or invalid (none of the above, suggesting test performed wrongly or a faulty test kit). A reactive or indeterminate INSTI test is not definitive; it requires confirmation with a serological test. The test is 99.6 % sensitive and 99.3 % specific [30]. The 'soft periphery' of the intervention was how this test was introduced and how it became embedded in the New Patient Health Check and wider organisational routines. As per trial protocol, each practice received a 90-min training session delivered by the research team and a consultant or specialist HIV doctor or nurse, comprising theoretical elements (rationale) and practical ones (rehearsing pre-test and post-test explanations, if possible with a simulated patient, and performing the test on samples under supervision). The practice lead for rapid HIV testing (nurse or health care assistant (HCA)) received an additional training session on study algorithms and quality assurance procedures. Quality control procedures were offered monthly for the first year of the trial and every 3 months in the second. Dedicated codes were installed on practice computers to capture rapid HIV testing as part of the New Patient Health Check or other consultations. Practices received a small one-off payment (£300) plus £10 per test performed, plus free testing kits and support. The New Patient Health Check is used mainly to collect baseline data on health and lifestyle from new registrants by asking standard questions led by computerised prompts. Raising the possibility of HIV to a new patient in a short, largely administrative appointment alters the nature of this appointment. Pre-test counselling is not provided, and there is no preliminary assessment of risk. Staff are encouraged to use standard phrases when explaining the test (and offering the opportunity to opt out), delivering it and giving provisional results. In the case of a 'reactive', 'indeterminate' or 'twice invalid' result, for example, staff were told to ask the patient to wait in the waiting or consultation room until the general practitioner was available to discuss the result with them and arrange confirmatory serology.

99.6 %. Considering a local prevalence of 2 in 1000 in the United Kingdom, this means that only 1 per 125,000 test results can be expected to be false non-reactive. Owing to the 3-month diagnostic window period, the test may fail to detect HIV in the early, acute phase of infection [29]. Patients with a non-reactive result with no recent risk can be assured of their negative HIV status immediately, whereas those with 'reactive' or 'indeterminate' results require confirmatory serological testing [30]. Potentially, then, HIV testing (serology or rapid or both) could be incorporated into the New Patient Health Checks that are currently routine in UK general practice [31].

The trial ran for 28 months between 2010 and 2012. Recruitment took place at 40 of 45 general practises practices in a socioeconomically disadvantaged London borough where the baseline prevalence of diagnosed HIV was 8 per 1000 adult population. Practices were randomised to an intervention arm (implementing rapid HIV testing alongside New Patient Health Checks) or a

control arm (usual care). The intervention is described in Box 1.

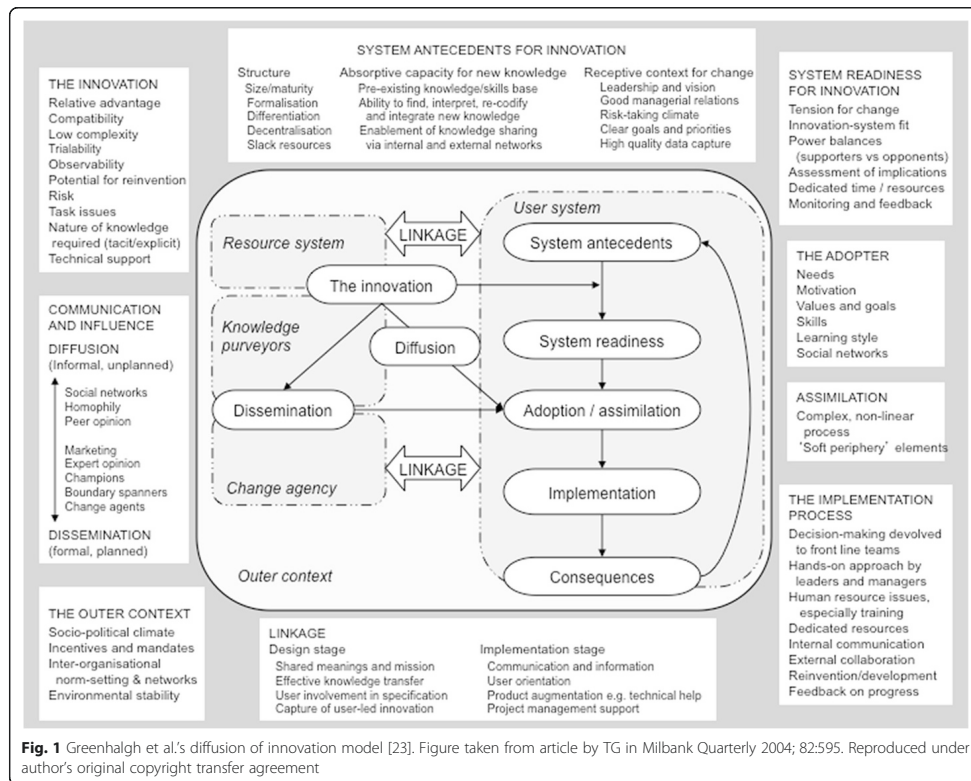
The primary outcome was timeliness of diagnosis on the basis of mean CD4 cell count of all patients newly diagnosed as HIV-positive in general practice, an indicator of stage of diagnosis. Overall, intervention practices offered 11,180 rapid tests, and 44.5 % of these were accepted. In total, 14 tests were reactive, of which 11 were confirmed to be HIV-positive. Serological testing [e.g., opportunistically by general practitioners (GPs) during routine consultations, and through antenatal screening] identified 21 (intervention) and 14 (control) further cases of HIV. Patients identified in intervention practices had higher CD4 counts (that is, were at an earlier stage of infection) than those identified in control practices [24, 25]. Of the patients diagnosed, 79 % were part of identified risk groups (63 % black African origin, 16 % men who have sex with men). All patients identified via rapid testing were successfully transferred to secondary care, and an economic evaluation showed that the intervention is likely to be cost-effective (unpublished data).

Despite the overall success of the trial and the positive result, there was marked variation between the 20 intervention practices in how many tests were offered and, of these, how many were accepted (see the Results section). This raised important questions and provided the impetus for a retrospective process evaluation of why some, but not all, practices were able to assimilate and sustainably implement rapid HIV testing as part of the New Patient Health Check, even though all had agreed to participate in the trial and knew that a goal of the trial was to increase testing.

**The diffusion of innovations model**

A wide-ranging systematic review of the diffusion, spread and sustainability of innovations in the organisation and delivery of health services identified six interacting components: (1) the innovation itself; (2) the intended adopters; (3) communication and influence; (4) the inner organisational or system context, comprising general antecedents for innovation-specific readiness for a particular innovation; (5) the outer (inter-organisational and environmental) context; and (6) the implementation process. The model (Fig. 1) emphasises the importance of linkage between different components of and feedback regarding the consequences of innovation to other parts of the system. The components of the model are defined in Table 1.

Applying this model to a RCT design is not straightforward, because the evidence on which it is based relates to free-living individuals operating in real-world conditions. In particular, the element relating to communication and influence was less relevant to this evaluation, because all practices and participating staff received a standardised training package (Box 1). Nevertheless, the pragmatic



design of the trial meant that many real-world influences were built into the study design. For example, participating practices were open to communication from other practices locally as well as from other, 'outer context' influences, such as the economic recession, new immigration and changes in national and local HIV policies.

The aspects of the model that were most relevant to the process evaluation were staff perceptions about the intervention (testing was undertaken by practice staff, who had different views about the value and appropriateness of the test and their own role in it), the organisational antecedents and readiness for innovation as well as the implementation and assimilation process.

**Methods**

**Management and governance**

Full details of study management and governance, including the independent data monitoring committee, are given in the main empirical report [24, 25]. The trial

(ISRCTN63473710) was approved by Camden and Islington Community Research Ethics Committee (09/H0722/67). Ethical approval for the qualitative research was gained from Bloomsbury National Research Ethics Service committee (11/LO/0324) in April 2011 with an amendment in December 2013.

**Data sources for process evaluation**

Various methodologies and data sources were used.

**Participant observation**

Throughout the trial period, HM was a member of the study team responsible for practice recruitment, training, monitoring and general liaison. This work required her to make frequent visits to practices, which were typed up formally as field notes as soon as was practicable after each visit. Numerous informal conversations and email exchanges also took place with practice staff regarding all aspects of implementation, including the

**Table 1** Definitions of components of Greenhalgh et al.'s diffusion of innovations model

Component	Definition	
Attributes of the innovation	How the potential adopter views the pros and cons of the innovation	
	<i>Relative advantage</i>	A clear, unambiguous advantage in terms of either effectiveness or cost effectiveness.
	<i>Compatibility</i>	Compatible with the values, norms and perceived needs or intended adopters.
	<i>Low complexity</i>	Composed of simple, easy to implement steps; able to be broken down and learned on an incremental basis.
	<i>Trialability</i>	Can be experimented with.
	<i>Observability</i>	Benefits are (or quickly become) visible to intended adopters.
	<i>Potential for reinvention</i>	Possibility to adapt, refine or otherwise modify the innovation to suit adopter needs.
	<i>Fuzzy boundaries</i>	If innovations have 'hard cores' (irreducible elements of the innovation) and 'soft peripheries' (structures and systems required for full implementation), adaptation of the soft periphery can facilitate adoption.
	<i>Risk</i>	Risks of the innovation (as perceived by the intended adopter) are outweighed by its perceived benefits.
	<i>Task issues</i>	Extent to which the innovation is relevant, feasible, workable and easy to use for the adopter.
	<i>Nature of knowledge</i>	Knowledge required to enact the innovation can be transferred, either by codification (explicit knowledge) or more informally, e.g., by shadowing (tacit knowledge).
<i>Technical support</i>	If the innovation is technical, help desk support is available, especially in the early stages of implementation.	
System antecedents for innovation (including structure and/or absorptive capacity and/or receptive context)	Extent to which the organisation is ready for innovations in general	
Structure	<i>Size and/or maturity</i>	Practice size is related to innovation adoption, with larger practices faring better regarding implementation; a proxy for other features, e.g., slack resources and functional differentiation.
	<i>Formalisation</i>	The extent to which there are rules and protocols regarding organisational activities which are upheld.
	<i>Differentiation</i>	The extent to which roles and activities are divided.
	<i>Decentralisation</i>	Decision-making power is appropriately dispersed across organisations.
	<i>Slack resources</i>	The resources an organisation has beyond what it minimally requires to maintain operations.
Absorptive capacity for new knowledge	A dynamic capability pertaining to knowledge creation and use that enhances an organisation's ability to gain and sustain a competitive advantage.	
	<i>Pre-existing knowledge and/or skill set</i>	Existing knowledge and skills within the organisation; particularly facilitatory if somehow related to the innovation.
	<i>Ability to find, interpret, recodify and integrate new knowledge</i>	The ability to take on, understand, integrate into existing systems and put into productive use new information.
Receptive context for change	<i>Enablement of knowledge sharing via internal and external networks</i>	Individuals are able to share knowledge regarding the innovation internally and externally through established networks.
	A combination of factors from both the inner and the outer contexts that together determine an organisation's ability to respond effectively and purposefully to change.	
	<i>Leadership and vision</i>	Top management support, advocacy of the implementation process and continued commitment to it enhance the success of implementation and routinisation.
	<i>Good managerial relations</i>	Staff have positive relationships with managers.
	<i>Risk-taking climate</i>	

**Table 1** Definitions of components of Greenhalgh et al.'s diffusion of innovations model (*Continued*)

		A supportive working culture where practice staff feel able to experiment with new innovations without fear of being reprimanded.
	<i>Clear goals and priorities</i>	Objectives are clear to the organisation and the staff.
	<i>High-quality data capture</i>	Organisational systems are in place to obtain high-quality data related to the innovation diffusion.
System readiness for innovation	The extent to which the organisation is ready for the specific innovation.	
	<i>Tension for change</i>	Degree to which adopters see the current situation as inadequate or intolerable.
	<i>Innovation system fit</i>	The innovation fits with existing values, norms, strategies, goals, skill mix, supporting technologies and ways of working within the organisation.
	<i>Power balances</i>	
	<i>Assessment of implications</i>	The implications of adoption are known and assessed.
	<i>Dedicate time and/or resources</i>	Degree to which budget and resources available are adequate and recurrent.
	<i>Monitoring and feedback</i>	Systems and skills are in place to monitor and evaluate the impact of the innovation and feedback to adopters.
Adopter	Those meant to adopt and enact innovations.	
	<i>Needs</i>	What the adopter needs to be able to adopt the innovation.
	<i>Motivation</i>	Whether the adopter is motivated to adopt the innovation.
	<i>Values and goals</i>	Does the innovation gel with the adopter's values and goals?
	<i>Skills</i>	The skills required to adopt the innovation and whether adopters possess these.
	<i>Learning style</i>	The ways that adopters learn are considered and catered to in the innovation training.
	<i>Social networks</i>	The patterns of friendship, advice, communication and support that exist among members of a social system.
Implementation process	The process by which a new innovation is diffused across an organisation.	
	<i>Decision making devolved to front-line teams</i>	Do lead users of the innovation have control over aspects of the implementation process?
	<i>Hands-on approach by leaders and managers</i>	Leaders and managers are involved in the implementation process, supporting and assisting problem solving as required.
	<i>Human resources issues, especially training</i>	Have all human resources issues linked to the introduction of the innovation (training, workload, supervision, performance management) been addressed adequately?
	<i>Dedicated resources</i>	Specific resources of time, budget and other relevant resource are dedicated to support implementation.
	<i>Internal communication</i>	Involved bodies communicate effectively with each other regarding the innovation and the implementation process.
	<i>External collaboration</i>	Effective knowledge-sharing links to other organisations who are implementing the same innovation.
	<i>Reinvention and/or development</i>	Was it possible to adapt the innovation or the tasks and processes associated with it to suit local contingencies?
	<i>Feedback on progress</i>	Are there evaluative and feedback mechanisms in place and enacted?

thoughts and feelings of front-line staff about HIV testing and their narratives of test enactment. This 'autoethnographic' approach is widely used in organisational case study research and can provide a particularly rich account of organisational culture and practices [32, 33].

#### **Qualitative interviews**

Semi-structured interviews were undertaken with a purposive sample of 21 staff in 16 of the 20 intervention practices; the other four practices failed to respond to requests. Most were nurses ( $n = 11$ ) or HCAs ( $n = 7$ ) who primarily offered the rapid HIV test as a part of the

New Patient Health Check. One practice manager, one clinical manager and one GP were interviewed in relation to their role in rapid testing (e.g., managing patients with reactive or indeterminate rapid test results, overall coordination of testing within the practice). Interviews were conducted at the practice during normal working hours and were one-to-one, except for two nurse and HCA pairs who asked to be interviewed together. Written informed consent was obtained from all participants, who also completed a short demographic survey regarding age, ethnicity, length of time at current practice, part-time or full-time employment and previous HIV-related experience. Interviews lasted between 30 and 60 min. Interviews were conducted throughout the final 8 months of the trial and into the following year. Participants were given a £10 voucher as compensation for their time.

Proust et al., in a feasibility and acceptability pilot study published prior to the trial, reported on patient views regarding rapid HIV testing in general practice [34]. Qualitative interviews with patients offered a rapid test as a part of the New Patient Health Check found that patients found the offer of a test acceptable and that they found the reduced wait time for results and the accessibility of testing to be appealing. Concerns included a possible lack of support for the newly diagnosed patient and patient preparation for testing [34]. Interviews are currently being undertaken with consenting patients who were diagnosed as HIV-positive through the trial and rapid testing. In a forthcoming article, we will report on patient diagnostic experiences of rapid HIV testing as part of the New Patient Health Check in primary care.

#### ***Trial performance at practice level***

Practice-level performance data were collected through the remotely accessible electronic record systems used in participating practices (EMIS [35] and VISION [36]). This allowed the research team to gather regular data on the number of rapid HIV tests offered, performed and declined at each practice. Upon completion of the trial, data were aggregated and overall trial performance was analysed. In addition, the number of HIV serological tests per practice (i.e., tests sent to the hospital laboratory either to confirm a rapid test result or for other clinical reasons) was compiled quarterly.

More generally, practice demographic data (including practice list size, index of multiple deprivation score, level of male serological HIV testing prior to the trial) were collated to enrich the case study and inform the application of the diffusion of innovations model.

#### **Data analysis and case study construction**

Data analysis occurred in two phases: (1) preliminary familiarisation and coding and (2) synthesis into case

studies. In the preliminary phase, qualitative transcripts (field notes, interviews and extracts from emails and documents) and matched demographic data on interviewees were uploaded into NVivo software (QSR International, Doncaster, Australia) and framework analysis was undertaken [37]. Selected transcripts (sampled for diversity and richness) were used to develop a preliminary coding frame. This framework was then applied to all transcripts, with emerging themes noted. Coding reports were generated. This process was applied twice. The first time it was designed to organise and gain familiarity with the data using the question, What were the experiences and perspectives of providers of rapid HIV tests in primary care? The second time it was used to bring in the components of the diffusion of innovation model (Fig. 1) to consider the question, What enabled or hindered providers in effectively implementing rapid HIV testing in general practice? After producing preliminary categories, we iteratively refined these in team discussions using the constant comparative method—that is, comparing each new item of data with an emerging picture of the case as a whole [38].

We created a spreadsheet of practice characteristics that included practice size, male HIV testing rate prior to the trial, rapid HIV and serological testing and practice HIV diagnoses during the trial period. One striking (and initially surprising) finding was that practices that had had high rates of male serological testing for HIV before the trial (a proxy for the level of prior awareness and interest in HIV in that practice) were not always high performers in rapid testing. This analysis informed the sampling of four contrasting case studies to help theorise the findings using diffusion of innovations:

- Practice A: high serological testing, high rapid testing
- Practice B: low serological testing, high rapid testing
- Practice C: low serological testing, low rapid testing
- Practice D: high serological testing, low rapid testing

Our aim in constructing the case studies was to produce a rich and meaningful account of how and to what extent the rapid HIV testing intervention was assimilated and implemented in each participating practice, all of whom showed enthusiasm for adopting the intervention. We used team discussions and applied narrative as a sense-making and synthesis tool to weave together the quantitative and qualitative findings for that practice into a rich picture that depicted key perspectives, events and upstream causes while also conveying ambiguities and uncertainties [39]. In this way, the strengths and weaknesses of each practice for the purposes of implementing the intervention were revealed and explored. We sent drafts of our interpretation to practices who

were interested in seeing them before finalising the interpretations presented below.

## Results

### Description of dataset and introduction to case examples

The final dataset for the process evaluation comprised 60 pages of field notes, 245 pages of interview transcripts and 70 pages of additional free-text documentation, plus quantitative data on the distribution of 11,000 rapid HIV tests across 20 intervention practices and 5193 serological (hospital laboratory) tests across 40 intervention and control practices, respectively.

### Common findings: relative advantage and simplicity of the rapid test

Despite wide variation in uptake of rapid testing between practices, there were some findings common to all, particularly in relation to the intervention (Box 1). The front-line staff who delivered the intervention almost universally perceived a distinct relative advantage (and considered that patients also saw an advantage) in rapid, accessible and convenient testing in general practice compared with usual care (the serological test requiring venepuncture and at least a 2-day wait for results). The quick and actionable results would mean less waiting and administration and, many staff believed, fewer losses to follow-up. Staff reported that patients appreciated receiving their results instantly, and they themselves gained satisfaction in being able to provide this information quickly.

Staff and patients felt that placing the rapid HIV test within the New Patient Health Check with an 'opt-out' option allowed people with low awareness of HIV and low concerns about testing to access a test easily, thereby extending the reach of testing.

*Interviewer: Do you think it's a good idea to test it in that way?*

*HCA: Yes, 100 %.*

*Interviewer: How come?*

*HCA: Because most people don't even think about it at all. They could go on their whole lives not thinking about it and people are quite—I don't know if 'ignorant' is the right word to use. If you offer somebody at a consultation on a one-on-one an HIV test, they might get a bit offended. But this way, if you're saying it's something that we're doing at this point in our practice, as a new patient joining us it's offered randomly, it just gives people a chance to think about if they do want it. If they decline, then at least they can come back and say, "You know, I was offered this test, and yes, I would like to have it done." – HCA from practice D*

Lack of need for pre-test and post-test counselling and detailed sexual history testing, as well as location of the test in the context of a routine general practice encounter, effectively normalised and destigmatised the rapid HIV test and made it relatively easy for non-specialist staff to learn and deliver (and for patients to accept). However, HCAs in particular do not routinely test for what is considered a stigmatised and serious condition, so the test did require some change in their role and the way they related to patients—an issue that played out differently with different staff and in different practices (see case studies below).

Staff also commented that patients preferred rapid finger-prick testing to venous blood sampling. The test was technically simple, and phlebotomy skills were not needed. Even patients who disliked needles did not seem to mind the small lancet used quickly in the rapid test, a finding we demonstrated previously in a pilot study [35]. They also said that patients preferred the near-patient test, as they could visibly see that the result was their own, thereby increasing their trust in the test result.

In sum, the INSTI HIV-1/HIV-2 Rapid Antibody Test (the 'hard core' of the intervention; see Box 1) was perceived extremely positively by the staff charged with delivering it. Below, we present four contrasting case studies of practices where different individual and organisational factors combined to produce four very different contexts for assimilating, implementing and sustaining the intervention for the duration of the trial.

### Practice A (high recruiter): high system antecedents, high system readiness

Practice A implemented the rapid testing intervention very successfully, offering more rapid tests than any other practice and having a moderate decline rate (42 %), though only one case of HIV was detected via the New Patient Health Check. Our qualitative and quantitative data showed that effective implementation of the test was the result of key system antecedents for innovation, high system readiness for the rapid test and a smooth implementation process and strong adopter factors among front-line staff (see Fig. 1).

Practice A was one of the largest practices in the borough. It was mature and well organised, with a clear differentiation of functions and staff roles and good managerial relations. For example, the practice nurse and HCA had been with the practice for some time. They felt their roles were clear, and they understood who should be called upon and at what stage if a test was reactive. Both expressed the importance of GPs in making diagnoses, both for the patient and for the sake of their own comfort in offering tests. If needed, they sought information and clarification from senior staff.



*I've had a couple of patients say that they didn't want the test at the time I offered it, in the New Patient Health Check, but is it okay if I go away, think about it and then maybe come back? And I've said, Well, you know, this is something that we offer now. If you come back, then I'd have to question that with the doctor as to whether you can have it as a, you know, fully registered patient. I've spoken, I did speak to a doctor actually, and they said that it would be okay if they hadn't been registered too far down the line. – HCA from practice A*

Junior practice staff were mentored by more senior staff, providing both pastoral support and opportunities for individual and team learning (the latter linked to the key construct of absorptive capacity; see Table 1). The practice was able to integrate new knowledge through regular practice meetings and feedback. Practice A showed interest in the monitoring of progress and the study's overall performance, often asking how they rated in relation to other trial practices.

Leadership, organisation and communication appeared to be strong factors in practice A. For example, a lead was assigned for the intervention and provided support to junior staff tasked with delivery. Roles were well differentiated, and support was provided promptly when required.

*Interviewer: But you've had a reactive?*

*Nurse: That was an early one.*

*HCA: Yeah.*

*Nurse: Trying to; I'm trying to recall it.*

*Interviewer: Okay.*

*Nurse: As to what, as to what I actually said. I remember I sent a screen message to (GP A), and I, I think I just said something like, oh, that I needed the doctor to verify the result and that I needed him to look at it. I think it was something like, that, it's such a long time ago now, and then (GP B) came in, and I had a chat with him, and we did the blood test, gave him some information, and I think (GP A) said that he would be in contact with him. – Nurse and HCA from practice A*

Staff in practice A perceived the intervention positively and were also proud of the overall quality of service they offered. They viewed the new test as enhancing that quality.

*Nurse: Yeah, I think, the impression I get is that they think that we're been quite thorough and that we're, you know, so I think it, I think it promotes us.*

*HCA: That we're very organised, well, she said I'm very organised and thorough.*

*Nurse: Yeah, that we care and that we're offering a good service. – Nurse and HCA from practice A*

Perhaps partly for this reason, rapid testing was quickly incorporated into the New Patient Health Check and was viewed by staff as a good fit with that process (a construct described in the literature as 'innovation–system fit' [23]). Practice A was also one of the few practices that did not stress time constraints (linking with what in the model is called 'slack resources', defined in Table 1).

Early in the trial, a positive HIV diagnosis through rapid testing was made, demonstrating that the innovation 'worked' and achieved its objective, an attribute known as *observability*. This is likely to have reinforced the implementation process (see feedback arrows in Fig. 1).

In sum, practice A illustrated many of the key organisational preconditions for successful assimilation of innovation, including key elements of structure (large practice list size, maturity, slack resources, functional differentiation), absorptive capacity for new knowledge (high pre-existing knowledge and skills base and formal and informal processes for knowledge sharing among staff from different professional groups) and high readiness to change (leadership and vision, good managerial relations, risk-taking climate and high-quality data capture). It also showed high readiness for the particular innovation (innovation–system fit) because clinicians were already interested in HIV testing and keen to promote it further. Importantly, nobody in the practice appeared opposed to the innovation.

#### **Practice B (high recruiter): moderate system antecedents, exceptional front-line staff, strong internal synergies**

Practice B also assimilated rapid HIV testing very effectively as part of the New Patient Health Check. Despite being one of the small to medium-size practices and having a low turnover of patients (and hence fewer new registrants), this practice diagnosed twice as many patients through rapid HIV testing as any other practice in the study. The number of rapid tests offered ( $n = 870$ ) was high for practice size, and the rate of tests declined was low (36 %). Yet, the serological testing rate prior to and throughout the trial was fairly low [fourth amongst the 40 (0.66/1000 serological testing rate during the trial period, and 2.07/1000 prior to the trial, respectively) participating practices prior to the trial], suggesting that the practice did not previously place significant emphasis on HIV testing. A number of factors at both the organisational and individual levels may help explain this success.

Practice B demonstrated moderate system antecedents and readiness for innovation (see Fig. 1). The practice was well organised and had a clear and harmonious differentiation of roles; the nurse spoke highly of senior doctors and vice versa. The practice also had high absorptive capacity for new knowledge and a receptive context for

change. This existing knowledge and willingness to learn more also point to the practice's goals and priorities of supporting patients beyond immediate medical needs. On one occasion when there was concern about misinterpreted results, the nurse immediately discussed next steps with the GP and ensured the safety of the patient. The good managerial relationships and strong communication shown here may also indicate a risk-taking climate in which interacting with innovations is encouraged and solutions to any challenges are found together when needed.

*Respondent: There was one which did ... that was indeterminate. There was ... you know, the pots. It was ... it was supposed to be non-reactive, but inside that pot it was like a line.*

*Interviewer: Okay. Right. Just a straight line.*

*Respondent: And when I told the doctor, he says, probably ... no, not the doctor; the lady that came the other day. He said probably it is damaged or something like that. But I told Doctor A, and he said I should call the patient back, you know. So, we call the patient back, and I explain, even to the patient as well, that this result, it doesn't mean you have HIV now, but it might be one thing or the other that is making the ... you know, the test to being invalid. So ... and she decided ... she came back.*

*Interviewer: Had another test.*

*Respondent: Yes. And it was non-reactive. – Nurse from practice B*

Although the practice had low serology rates prior to the trial, once testing was introduced and the staff were trained, the intervention was quickly adopted. Staff appeared engaged, seeing the relative advantage of the innovation.

An unusual feature of practice B was that a single individual (the practice nurse) undertook all New Patient Health Checks, for which she had a generous time allocation (30 min for each). She worked full-time and had her own dedicated consultation room. She had a professional and strongly patient-centred approach to her job, working largely autonomously and indicating general enjoyment of what she did.

The nurse who did all the rapid testing framed it not merely as a service for individual patients but also as an ethical imperative and a way to improve public health; in other words, it had particularly high value and significance for her as a professional.

*I think I just like doing it because it is good. When you think about the end result, is good. It makes you feel you have done something good as well. At least for somebody who doesn't know that is positive and is not, because although the news of being positive, it has a*

*lot of effect on them, but after counselling... But I believe it will prevent other people as well, or protect other people. Either prevent or protect from catching it because if it is known, then the patient can take precaution not to infect other people. – Nurse from practice B*

Quality control visits showed that the lead nurse for rapid testing, along with other practice staff, managed to 'reinvent' the test and the algorithm to suit local practice conditions without losing fidelity. The nurse felt concerned at the potential effect of a reactive result on the patient in the room, so the nurse began to perform the definitive aspect of the test away from the patient's view—an adaptation that was not in the original training. She did not disclose to the patient that the test took 1 min, allowing herself a few moments when required to reflect on test results and plan her next steps.

*Interviewer: Yes. How did you feel the first time you saw a reactive?*

*Nurse: I was ... but I was looking, but he wasn't looking at me.*

*Interviewer: Yes, because you do it on that side of the room.*

*Nurse: Yes. On that side. So he was sitting down there, so ... but he was looking at me as well. But because I was facing that side, he couldn't see my face. – Nurse from practice B*

Another adaptation in practice B was that GPs would refer patients to this nurse for rapid testing, regardless of whether they were booked for a new patient check. The nurse reported that some patients for whom the possibility of HIV infection was being considered were persuaded to have the rapid test when they may have declined the more invasive and less convenient serological testing.

As in practice A, a positive HIV diagnosis through rapid testing was made early in the trial, reinforcing staff confidence in the test.

Practice B is noteworthy, not merely for possessing many (though not all) key system antecedents and readiness factors for innovation and highly motivated front-line staff, but also in the way these elements were combined. The very professional and patient-centred practice nurse, for example, was able to give her very best to the study because the practice allocated plenty of time and allowed the nurse to work independently and adapt the innovation to suit her own working style and local microroutines. More subtly, the culture of the practice was to embrace innovations and support their embedding. Doctors recognised the nurse's competence and interest in this innovation and began to send her



additional patients for testing. In these and numerous other ways, the elements of innovativeness built on one another synergistically.

**Practice C (low recruiter): low system antecedents, reluctant front-line staff**

Practice C struggled to implement rapid testing. The practice was slow to offer the first test, and its rate of testing remained low throughout the study (in total, 72 rapid tests were offered, and 50 % of these were declined), despite multiple visits and 'retraining' from the research team. It had a low serology HIV testing rate prior to and throughout the trial. Low recruitment from this practice was explained by a combination of factors, both organisational and individual.

System antecedents were low in practice C. A small practice, it comprised three GPs, one nurse and one HCA (both of whom undertook New Patient Health Checks), one practice manager and two receptionists. Located within a large building housing multiple practices, the surgery; always seemed crowded and very busy.

The practice showed little interest in, or time to accommodate, other innovations, and there were few resources (human or financial) available to invest in new projects. Overall, the practice appeared to find a new service model difficult to integrate into business as usual. There was expressed frustration with changing National Health Service (NHS) policy and guidance as well as broader changes in health care culture. A low absorptive capacity for new knowledge was also evident. One of the doctors, for example, asked the research team how to access information and register for GP training courses unrelated to the intervention, suggesting that this individual found locating and navigating information difficult. Significantly, practice staff did not perceive a great need for HIV testing in the borough, suggesting that there was little, if any, tension for change. The nurse described herself as 'overstretched'. She gave the impression of barely being able to complete her existing work and having almost no personal capacity for additional tasks:

*[The rapid HIV test] really is not a problem. It's just, you know, having the time. I mean, often I get to the end of a morning, and I feel like a rag. – Nurse, practice C*

Because of the understandable reluctance of busy front-line staff to accommodate the test, it never became routinised within the New Patient Health Check in practice C; it was not offered to most patients having these checks, and, unlike in practices A and B, it never came to be viewed by staff as *part of* that check. With such

low numbers of tests being undertaken, it was not surprising that no cases of HIV were detected using rapid testing, so its observability was not evident in this practice.

Our data suggest that there may also have been an issue about the compatibility of the test with the values of the HCA, who appeared personally uncomfortable testing for HIV. Indeed, it is unclear whether this staff member offered any tests throughout the trial period. This was a source of frustration to the nurse, who had tried to rectify the situation:

*I don't have any problem with doing [the rapid HIV test]; the actual doing of the tests is straightforward. My colleague who should be doing them as well hasn't done one. I don't know. I went through it with her again a while ago; I don't know, two or three weeks back I went through it again with her to remind her how to do it. And I do it whenever I can, but my problem is time... I don't know if it's a religious thing, maybe [explanation of perceived religious views of colleague]. I don't know if it's something to do with that. But she's a health care assistant; she's not a nurse. That's a difference as well. – Nurse, practice C*

The nurse raises an important point here—that the rapid HIV test was not merely a technical procedure but a professional interaction. Technically, it was simple and straightforward (albeit hard to accommodate if time was short), but because of its link to a stigmatising illness, it also required a professional, rather than merely transactional and task-oriented, relationship with the patient. Implicitly, the block to adoption may not have been the HCA's views per se but the fact that her role—in this practice, at least—was not professionalised. HIV remains a stigmatised condition, and the line between a screening test and a diagnostic test can be fine, particularly in the case of the test used in the trial, which may be interpreted by patients as well as providers (two dots as a reactive result, one dot as a non-reactive result). It may have been that reluctance to offer rapid testing relates to the need to provide immediate feedback regarding test results. Whereas GPs are called upon to share test reactive results, HCAs and nurses expressed significant concern about managing reactive results and patient reactions as well as the interval between the test and calling upon the GP. This may have been a factor in the HCA's reluctance to test. The nurse, though personally motivated and more professionally experienced, had only limited opportunity to offer rapid HIV testing, as most New Patient Health Checks were performed by the HCA.

It is also significant in the quotation above that the nurse took personal responsibility for trying to change

the HCA's attitude and behaviour in relation to rapid testing. Despite raising the issue with GPs and the practice manager, no action was apparently taken to explore or improve this staff member's low performance on trial activities. In contrast to the subtle but important involvement of senior clinicians and managerial staff in practices A and B, the approach of similar staff in practice C was distinctly 'hands off'.

It is noteworthy that the practice nurse made numerous efforts to implement the rapid test, but those efforts had very limited success in the context described above. For example, she showed creativity in 'reinventing' the finger-prick aspect of the test. (*"As long as I get a decent drop of blood, just occasionally people don't bleed terribly well. I don't like the finger-pricker they give with it. I tend to use my ones.... They're a bit more gentle."*) This motivation and creativity did not translate into tests actually performed, however, because most New Patient Health Checks were done by someone else, and the low absorptive capacity of the practice meant that the nurse's improved method of testing was not effectively shared with the front-line staff member who had the most opportunity to actually do the test.

In sum, practice C was not an innovative practice, nor was it ready for the specific innovation of rapid HIV testing. The member of staff on which the intervention most depended was personally reluctant, and factors known to help the implementation phase (notably hands-on input from senior staff) were absent. In this environment, the presence of a single, keen and committed member of staff had only limited impact on the implementation of the intervention.

#### **Practice D (low recruiter): keen doctors but low system antecedents and negative synergies**

Practice D also struggled to implement rapid HIV testing as a part of the New Patient Health Check. The 557 rapid tests that were offered during the trial period (of which 43 % were declined) may appear relatively high, but the size of the practice and consistent registration of new patients demonstrated a number of missed opportunities for testing. The pattern of testing over time suggests that the innovation was never effectively routinised. Rather, periods with very low rapid testing were interspersed with periods in which a number of tests were performed within a short period of time.

On the surface, this low recruitment rate was surprising. Several of the GPs had a clinical interest in HIV; HIV serological testing rates were high both before the trial and during it (696 performed); and a high turnover of patients ensured high numbers of New Patient Health Checks.

As one of the largest and most diverse practices in the borough, practice D comprised 15 GPs, 9 nurses, 3

HCA's, 2 practice managers and more than 10 receptionists and administrators. Many staff worked part-time. There was time pressure on many activities, and the practice was constantly busy. The striking contrast between the very high HIV serology rates but very low rapid testing rates may be related to our finding that there were two distinct work cultures within the practice. Many of the GPs were highly qualified with some involved in community-based projects. Others had an interest in sexual health and regularly offered opportunistic regularly offered opportunistic serology testing for HIV.

However, the nurses and HCAs appeared to have little or no involvement in these activities or protected time to become involved. Knowledge appeared to circulate well among the doctors, but to a much more limited extent between the doctors and the other practice staff, suggesting a problem with absorptive capacity (see the Discussion section). In general, non-medical staff did not have academic links. Many worked part-time and had a very task-oriented attitude toward their work (i.e., they came to work, completed what was expected of them and went home). Some staff described a lack of harmony in practice relationships as well as a sense of being personally overstretched. There appeared to be relational tensions between some staff in the practice that affected the implementation of the study protocol. For example, HCAs had asked reception staff to hand out leaflets about the study to patients at the reception desk, but this did not always happen. Unusually, the research team assisted in mediating this issue.

Although front-line staff expressed enthusiasm about providing testing and acknowledged the value of offering the test, they also viewed involvement in the trial as an additional task in their already high workload. The doctors in practice D viewed involvement in this trial as important both for them as professionals and for the practice population, but they did not appear to discuss with front-line staff how the innovation could successfully be incorporated into an already busy practice. As a result, opponents of the innovation ('yet another task') outnumbered supporters, and because it was nurses and HCAs who actually delivered the intervention, these individuals were more strategically placed to do so. Bursts of trial activity probably reflected periodic encouragement of front-line staff by GPs concerned to increase the practice's performance statistics, but this is very different from *routinising* the innovation as business as usual (see the Discussion section).

Although decision making about offering the rapid test was largely devolved to front-line teams, this was complicated by poor communication and strained relationships, to the extent that front-line staff did not appear inclined to take responsibility for implementation. There

was also a significant problem with time and resources because HCAs were often called upon to refocus their work for short periods to meet particular practice goals. There was little inter-practice feedback unless it was prompted by the study team, minimising opportunities for creating the kind of positive feedback loops that were evident in practices A and B.

These organisation-level factors significantly overshadowed other, more positive elements of this practice in relation to HIV testing, including the perceived relative advantage of the rapid test in comparison with the widely used serological testing, and the compatibility of the test with the values and goals of the practice. In addition, whilst most front-line staff found the test simple and easy to use, one HCA (unusually) reported struggles with the material aspects of the test and indicated that, on some occasions, this stopped her from offering testing. Even HCAs who expressed strong enthusiasm for testing felt they were often unable to offer tests, however, owing to a lack of time as well as a lack of continuity in their role.

*But because it was coming up to the end of the financial year and everyone had to tally up QOF points for diabetes and these and this and that, it took priority. If people had come in, obviously if there were new patients, we wouldn't turn anybody away, but we were phoning up and pre-booking patients to come in for their diabs or their foot checks or their blood pressure. And because I'm only now doing 3 days a week, I literally split sessions between here and (another practice). I do here three sessions and there three sessions. So, when I am here, they get me to do loads of ECGs and different other things, and then when I'm there, I'm doing things over there that they need doing. – HCA, practice D*

Moreover, despite a number of HIV diagnoses made using serological testing, no diagnoses were made using rapid tests, indicating a lack of observability. It is telling that, whereas doctors in practice B altered their behaviour during the trial by sending patients to the nurse for rapid HIV testing, those in practice D continued to use serological testing when they suspected possible HIV in a patient. It appears that the rapid testing was seen as the province of a different group of staff, not something that was business as usual. GPs become involved in the rapid HIV testing algorithm in cases of reactive, indeterminate or invalid results, but because none occurred at practice D, this may have impacted their knowledge and involvement in trial activities.

In sum, despite much initial enthusiasm, practice D was impeded by a combination of structural, capacity-related and cultural factors (most crucially, limited slack

resources), along with individual adopter traits and a weak process of implementation.

## Discussion

### Summary of findings

This process evaluation of a complex intervention trial in UK general practice has demonstrated the usefulness of the diffusion of innovations model in explaining variation in performance of participating practices. In particular, five aspects of the model appeared to distinguish high-performing practices from low-performing ones.

### System antecedents for innovation

Larger, more formally organised practices with an appropriate division of roles and slack resources (especially time), as well as those with strong communication networks and good managerial relations, were higher recruiters.

### System readiness for the innovation

Practices with well-organised New Patient Health Checks, clear and stable staff roles for these checks, that had many supporters of rapid HIV testing and that were able to dedicate time and resources to incorporating the test smoothly into practice routines were better able to implement testing.

### Adopter characteristics

Staff who perceived the test to be beneficial to patients, easy to undertake and professionally meaningful undertook more tests.

### The implementation process

Uptake of the intervention was smoother and more likely when both senior clinicians and managers took a hands-on approach. If practices devolved decision making to front-line teams but did not follow up with support and feedback, implementation suffered. Dedicated resources such as time, space and support for implementation appeared critical.

### Reinvention and local customisation

Small adaptations to how, where and by whom the test was conducted, without losing fidelity of the core components, sometimes appeared to make a significant difference to its acceptance and routinisation within the practice, though reinvention alone sometimes failed to overcome wider structural or cultural barriers.

Despite the good fit between individual components of the model and our case study data, it is important to stress that our findings also illustrate how these components may (but do not always) act synergistically and interact dynamically, allowing strengths in one component to compensate for limitations in another. Conversely, the presence of individual elements conducive to innovation

does not guarantee success, since the overall practice dynamic may prevent particular factors from having a positive influence. This is important because it means that, whilst all the elements described above are 'evidence based', the way they play out in any particular organisation will be hard to predict.

Additionally, as acknowledged by Greenhalgh et al. in their discussion of the diffusion of innovations, greater consideration of the transferable lessons from cognitive and social psychology is needed [23]. Models of innovation diffusion are based largely on a dyadic interaction between a single adopter and an intervention. Rapid testing in primary care produces a triad between the provider (the adopter), the rapid test (the innovation) and the patient. We found that in many cases the views and actions of providers depended on their assumptions about patient feelings and reactions to the offer of a rapid HIV test.

*When we did the training, we were sort of told, with the reactive result, you are to leave the room and get a doctor. I haven't had to do that yet, but I don't know how that would make the patient feel, if I am just getting up and walking out.... I mean, I don't think it was as abrupt as all that in the training.... I don't know how people feel about that, but obviously something is going on.... Would I just make them more nervous? – HCA*

Unsurprisingly, this provider 'theory of mind' regarding the patient entered the calculus of offering testing and was a strong aspect of the discussion of the innovation. We feel this is an underdeveloped aspect of the diffusion of innovations model which precludes a more nuanced discussion of the health care consultation, the role of the patient and the impact of new innovations within it.

#### **Implications for involving organisations in complex intervention research**

Our findings support the conclusion that there is not, nor can there ever be, a universal implementation model for complex interventions. Site-specific characteristics and realities need to be considered. Complex interventions, such as other service-level innovations, cannot be treated as 'bolt-ons', but must instead be carefully integrated with practice systems to become part of business as usual. This process is known as 'routinisation'. An organisational routine is a recurrent, collective, interactive behaviour pattern implemented (often largely subconsciously) by individual actors through shared knowledge and practice [40]. Routines are path-dependent; that is, they are shaped by historical particularities in any given setting, so there is no such thing as universal best practice. Whilst routines confer stability in an organisation by conveying a strong sense of what is 'business as usual',

they also contain within them the seeds of change because they depend for their enactment on here-and-now decisions by individual actors whose creativity can allow a change to the routine (and hence 'reinvention' of the complex intervention).

Practices who were successful in implementing the rapid HIV test as part of the trial had routinised the innovation not merely by assigning its component tasks to particular staff members but also by encouraging and rewarding those staff for embedding it in the day-to-day work of the practice and linking it to other routines. This crucial distinction between 'complex intervention as a set of tasks' and 'complex intervention as embedded routine' aligns with Denis et al.'s notion of the 'hard core' of a complex intervention (the elements that constitute its 'fidelity') and the 'soft periphery' which can and must adapt to accommodate it [16]. In cluster randomised trials, the unit of intervention is large (an entire organisation, as opposed to individual participants), so poor uptake of the intervention by one participating unit can significantly threaten the success of the trial [5].

We cautiously conclude that one way in which researchers might guard against such eventualities would be to meet with practices prior to recruitment and use the diffusion of innovation framework to consider the different 'soft periphery' aspects for the proposed intervention. General practices are diverse spaces and vary widely even within a small geographic locality. Much may be gained from highlighting the practice's strengths and weaknesses in relation to a particular innovation ('assessment of implications' in Fig. 1).

Such an assessment should include, for example, consideration of what is acceptable research 'fidelity'. Pragmatic trials are meant to account for the contextual factors implicated in the 'real-life' settings where trials are conducted [6]. In diverse settings such as general practice, greater consideration of how we define research fidelity may be required. As discussed by Hawe and Shiell, 'fidelity defined functionally rather than compositionally' may be key [15]. The point is to allow the interventions to be responsive to their context while still being meaningfully evaluated.

Perhaps drafting site-specific mini protocols outlining how fidelity could be maintained while also accommodating contextual issues could be considered. It may, for example, mean allocating testing to a particular nurse or HCA who sees the value in offering testing, finds the test easy to deliver and enjoys new tasks, or (in busy practices) extending the time allocated to the New Patient Health Check, at least in the early stages.

Another, more general way for research teams to guard against poor uptake of interventions by participating units is to address the issue of slack resources. Perhaps unsurprisingly, successful practices in our trial tended to

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## Promotion of rapid testing for HIV in primary care (RHIVA2): a cluster-randomised controlled trial



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### Summary

**Background** Many people with HIV are undiagnosed. Early diagnosis saves lives and reduces onward transmission. We assessed whether an education programme promoting rapid HIV testing in general practice would lead to increased and earlier HIV diagnosis.

**Methods** In this cluster randomised controlled trial in Hackney (London, UK), general practices were randomly assigned (1:1) to offer either opt-out rapid HIV testing to newly registering adults or continue usual care. All practices were invited to take part. Practices were randomised by an independent clinical trials unit statistician with a minimisation program, maintaining allocation concealment. Neither patients nor investigators were masked to treatment allocation. The primary outcome was CD4 count at diagnosis. Secondary outcomes were rate of diagnosis, proportion with CD4 count less than 350 cells per  $\mu\text{L}$ , and proportion with CD4 count less than 200 cells per  $\mu\text{L}$ . This study is registered with ClinicalTrials.gov, number ISRCTN63473710.

**Findings** 40 of 45 (89%) general practices agreed to participate: 20 were assigned to the intervention group (44 971 newly registered adult patients) and 20 to the control group (38 464 newly registered adult patients), between April 19, 2010, and Aug 31, 2012. Intervention practices diagnosed 32 people with HIV versus 14 in control practices. Mean CD4 count at diagnosis was 356 cells per  $\mu\text{L}$  (SD 254) intervention practices versus 270 (SD 257) in control practices (adjusted difference of square root CD4 count 3.1, 95% CI -1.2 to 7.4;  $p=0.16$ ); in a pre-planned sensitivity analysis excluding patients diagnosed via antenatal care, the difference was 6.4 (95% CI, 1.2 to 11.6;  $p=0.017$ ). Rate of HIV diagnosis was 0.30 (95% CI 0.11 to 0.85) per 10 000 patients per year in intervention practices versus 0.07 (0.02 to 0.20) in control practices (adjusted ratio of geometric means 4.51, 95% CI 1.27 to 16.05;  $p=0.021$ ). 55% of patients in intervention practices versus 73% in control practices had CD4 count less than 350 cells per  $\mu\text{L}$  (risk ratio 0.75, 95% CI 0.53 to 1.07). 28% versus 46% had CD4 count less than 200 cells per  $\mu\text{L}$  (0.60, 0.32 to 1.13). All patients diagnosed by rapid testing were successfully transferred into specialist care. No adverse events occurred.

**Interpretation** Promotion of opt-out rapid testing in general practice led to increased rate of diagnosis, and might increase early detection, of HIV. We therefore recommend implementation of HIV screening in general practices in areas with high HIV prevalence.

**Funding** UK Department of Health, NHS City and Hackney.

### Introduction

Timely diagnosis of HIV is a major challenge. Undetected HIV and late diagnosis are associated with ill health, increased risk of death from HIV/AIDS, and onward viral transmission, constituting a substantial burden to public health budgets worldwide.<sup>1-3</sup> Of 107 800 people with HIV in the UK, almost one quarter are undiagnosed,<sup>4</sup> 42% are diagnosed late (after they should have begun antiretroviral treatment, CD4 cell count <350 cells per  $\mu\text{L}$ ), and 24% are diagnosed very late (CD4 cell count <200 cells per  $\mu\text{L}$ ).<sup>4</sup> Likewise, roughly half of the 2.2 million people with HIV in Europe and a sixth of the 1.1 million people with HIV in the USA are undiagnosed.<sup>1,5,6</sup>

Expansion of HIV testing is key to improving HIV outcomes. In 2008, the British HIV Association recommended universal HIV testing in primary care in areas with high prevalence (>0.2%), in addition to routine

screening programmes in antenatal care and sexually transmitted infection clinics.<sup>7</sup> This approach was endorsed by the National Institute for Health and Clinical Excellence.<sup>8,9</sup> Pilot projects have shown the acceptability and feasibility of HIV testing in primary care.<sup>10-12</sup> However, HIV testing in these settings has not been widely adopted; there is no evidence about outcomes from robust screening trials. The US Preventative Services Task Force has noted that “no randomised trial or observational study compared clinical outcomes between adults and adolescents screened and not screened for HIV infection”,<sup>13</sup> a conclusion also reached by the National Institute for Health and Clinical Excellence.<sup>8,9</sup> To our knowledge, no randomised trials have shown that HIV screening leads to increased and earlier diagnosis. This is a key evidence gap in current guidance.<sup>14,15</sup>

Primary care is ideally placed to offer HIV testing.<sup>7</sup> General practices provide health checks for newly

Lancet HIV 2015

Published Online  
April 29, 2015  
[http://dx.doi.org/10.1016/S2352-3018\(15\)00059-4](http://dx.doi.org/10.1016/S2352-3018(15)00059-4)

See Online/Comment  
[http://dx.doi.org/10.1016/S2352-3018\(15\)00064-8](http://dx.doi.org/10.1016/S2352-3018(15)00064-8)

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**Research in context****Evidence before this study**

We searched PubMed for randomised controlled trials, published from Jan 1, 2000, to Jan 31, 2015, testing the effects of screening of adults for HIV in primary care compared with usual care on rate of diagnosis, CD4 count, and disease stage at diagnosis. We found no studies that met these criteria. The US Preventative Services Task Force did a similar search in 2011, as part of their evidence review to update their 2005 recommendations on HIV screening. They noted that “no randomised trial or observational study compared clinical

outcomes between adults and adolescents screened and not screened for HIV infection”.

**Added value of this study**

These findings provide, to our knowledge, the first robust evidence from a randomised study that a screening programme leads to increased rate of HIV diagnosis.

**Implications of all the available evidence**

Public health leaders should consider implementing screening for HIV in primary care in high prevalence areas.

registering patients and are a referral point to specialist care. HIV testing in general practice is feasible and acceptable<sup>10–12</sup> and might be preferable for people who would not normally attend traditional HIV testing settings such as sexual health clinics.<sup>11</sup>

We did a pragmatic cluster-randomised controlled trial to test the hypothesis that a multifaceted educational outreach programme promoting rapid HIV testing in general practice leads to increased and early diagnosis of HIV. We used a cluster-randomised design because the intervention was directed at practices, rather than individual patients.

**Methods****Study design and participants**

We did this cluster-randomised controlled trial in general practices in Hackney, a multiethnic, socioeconomically deprived inner London borough, which has the ninth highest prevalence of diagnosed HIV infection (eight patients per 1000 adults) in the UK.<sup>1</sup> We invited all general practices in Hackney to participate. At entry, practices offered incentivised serology testing for HIV to patients attending sexual health checks and did opportunistic serology testing when clinically indicated. Visiting midwives offered HIV screening for women receiving antenatal care. The study was approved by Camden and Islington Community Research Ethics Committee and ran from April 19, 2010, to Aug 31, 2012. An independent data monitoring committee was established.

We included patients aged 16 years (the age of consent for medical procedures in the UK) and older, who newly registered with study practices, and who were able to have a pretest discussion in English or with a suitable translator. Information sheets, available in English and eight locally spoken languages, were displayed at reception desks. The ethics committee approved a process of valid implied consent for patient participation.<sup>12</sup> We excluded patients who could not understand the information sheet or engage with the pretest discussion for HIV testing, and those who were HIV positive.

**Randomisation and masking**

Practices were randomly assigned (1:1) between April, 2010, and August, 2011, to either intervention or control,

by an independent clinical trials unit statistician with use of a minimisation program (Minim, version 1.3),<sup>16</sup> maintaining allocation concealment. Minimisation criteria were practice list size (<5000, 5000–7000, or ≥7000 registered patients); practice deprivation (Index of Multiple Deprivation score: <47 or ≥47);<sup>17</sup> and male HIV testing rate (men tested between April and October, 2009/ men registered × 1000: less than seven or seven or more). Both total HIV testing rate and female HIV testing rate would have been confounded by the unknown contribution of antenatal HIV screening by midwives. Therefore, the male HIV testing rate offered the best representation of how actively each practice screened for HIV. Neither investigators nor clinical teams were masked to allocation.

**Procedures**

The intervention consisted of a practice-based outreach educational programme with follow-up training for a nominated HIV lead nurse or health-care assistant in each practice, integration of rapid HIV testing into the registration health check and management of reactive tests, and provision of free rapid HIV tests and payment of £10 per test completed. Control practices provided usual care only, which included an offer of serology HIV testing opportunistically and on patient request.

The educational programme was based on published clinician behaviour change strategies<sup>18–20</sup> together with our experience of delivering similar interventions. Initial training sessions were held at individual practices, lasted 90 min, targeted the whole practice team, and included didactic and interactive elements. Session leaders (WL, HM) were trained to ensure intervention fidelity (appendix p 1). Rapid HIV test operators completed competency-based training. An HIV lead was nominated in each practice to coordinate rapid testing and quality assurance (appendix p 2).

Registration health checks were done by a nurse or health-care assistant, who followed prompts on a template in patients' electronic health records. We added prompts to offer rapid HIV testing, linked to bespoke Read codes to record test outcomes: non-reactive, reactive, indeterminate, invalid, and test declined. Read

See Online for appendix

For Read codes see  
[http://systems.hscic.gov.uk/  
data/uktc/readcodes](http://systems.hscic.gov.uk/data/uktc/readcodes)

coding enabled remote data collection for testing activity (appendix p 2). The INSTI HIV1/HIV2 Rapid Antibody Test (bioLytical Laboratories, Canada) finger prick system was used for rapid testing.

The intervention was adaptable to each individual practice: staff could additionally offer rapid HIV testing in a range of clinical settings (eg, sexual health checks) and were encouraged to continue opportunistic HIV testing by serology. The core components of the testing process included an offer of a rapid HIV test as part of routine new registration health checks including a pretest discussion for patients to make informed decisions about testing; a rapid HIV test followed by a discussion for patients with non-reactive tests; and an immediate notification by the rapid test operator to the general practitioner of any patient with a reactive, indeterminate, or twice invalid test results with confirmatory serology sampling, and follow-up by a general practitioner (appendix p 2).

Any venous blood sample detected as reactive to HIV-1 or HIV-2 on an Abbott Architect ci8200 analyser (Abbott Diagnostics, UK) at Homerton Hospital (London, UK) was sent on to Barts Health Virology for confirmatory testing with the VIDAS HIV DUO Quick assay (BioMerieux, UK) and the ImmunoComb II HIV 1 & 2 BioSpot kit assay (Alere, UK).

HIV-positive patients were referred to Homerton Hospital for specialist care. Practices implemented rapid testing immediately after the educational session. Ongoing support from the education team was available via telephone or email to practice staff for queries related to rapid testing. Control practices were informed by email about current national guidance on HIV testing. All study practices continued to provide standard care of HIV testing and were supported by a community HIV liaison nurse.

At Homerton Hospital, all patients who tested HIV positive at participating practices were allocated a unique study number. Newly diagnosed patients were distinguished from known HIV-positive patients already in care or defaulted from specialist care with the Genitourinary Medicine Clinical Activity Dataset.<sup>21</sup> The Homerton clinical team (JA, SM) extracted clinical record data into anonymised confidential clinical case report forms. AM, who was masked to study allocation, verified the accuracy of data extraction for all patients before data were passed to the study statistician (appendix p 4).

We generated rapid HIV antibody test result codes for the trial: EMISNQRE117 (reactive), EMISNQNO26 (non-reactive), EMISNQIN61 (indeterminate), and EMISNQIN62 (invalid). We also used the following Read codes: HIV (serology) screening test (4JR7) and rapid HIV test declined (8I3P). The Clinical Effectiveness Group at Queen Mary University of London (KP, MAS, AC, and JD) remotely extracted rapid HIV testing data and serology testing data from general practice computer systems (EMIS, Egton Medical Information Systems, UK; and Vision, In Practice Systems, UK).

## Outcomes

The primary outcome was mean CD4 count of newly diagnosed patients (see appendix p 4 for a definition of a newly diagnosed patient). We included women newly diagnosed with HIV by the UK Antenatal HIV Screening Programme. We excluded patients who had not been tested for HIV before specialist referral, and patients who were referred by their general practitioner to secondary care at Homerton Hospital either for HIV testing or for further management of a suspected HIV-related illness. Secondary outcomes were rate of new HIV diagnoses (patients diagnosed/year/10000 practice list size), percentage of patients with CD4 count less than 350 cells per  $\mu\text{L}$ , and percentage of patients with CD4 count less than 200 cells per  $\mu\text{L}$ .

The original primary outcome was the number of new HIV diagnoses. However, our initial assumptions were based on few data and the number of new diagnoses early in the study was lower than expected. Thus, on June 14, 2011, with the approval of the data monitoring committee, we recalculated statistical power with CD4 count as the primary outcome, retaining numbers of new diagnoses as the main secondary outcome.

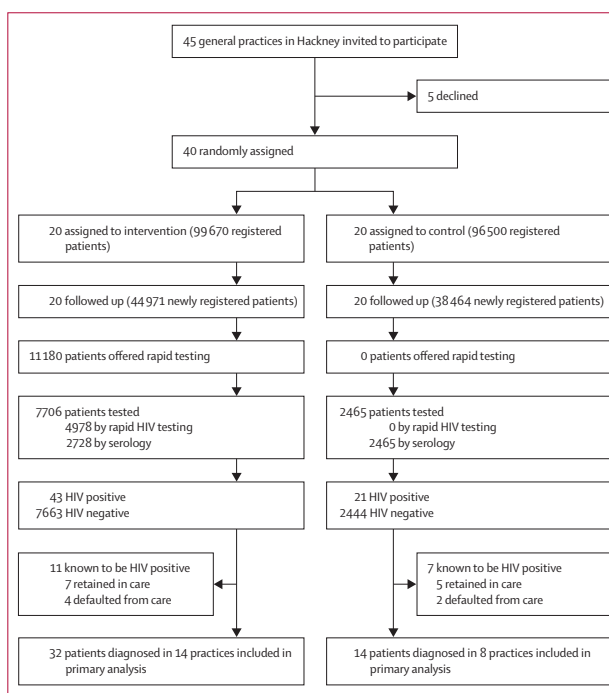


Figure: Trial profile



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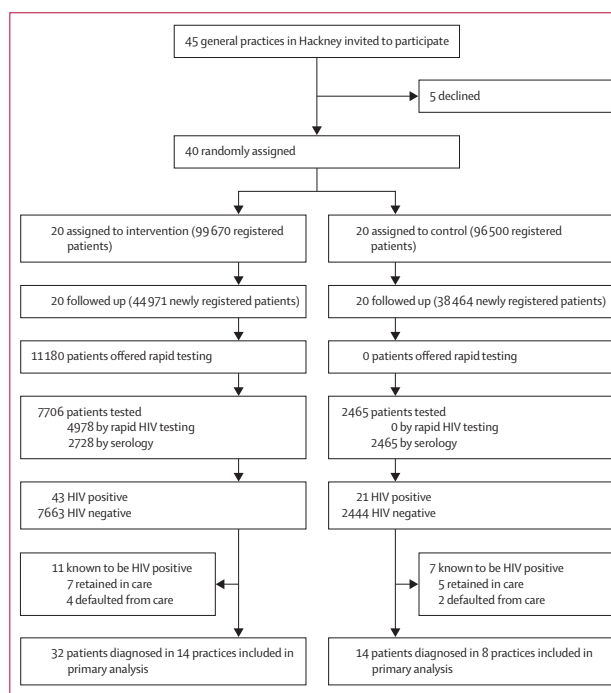


Figure: Trial profile

### Statistical analysis

Allowing for clustering, and assuming 20 practices in each group and analysis of CD4 on the square root scale with an SD of 6 and an intracluster correlation coefficient of 0.05, we expected to identify 72 new HIV diagnoses, with 80% power and 5% significance. This would be sufficient to detect an increase in the mean CD4 count from 300 cells per  $\mu\text{L}$  to 470 cells per  $\mu\text{L}$ , corresponding to a reduction in the proportion of late presenters from 30% to 10%. We made allowances for practices to identify different numbers of patients or none at all.<sup>22</sup>

We compared intervention and control groups with logistic regression adjusted for clustering. We estimated the effect of the intervention on CD4 count and rate of diagnosis with a linear regression model adjusted for clustering of practices in Stata (version 12) by use of the cluster option (except for rate of diagnosis, for which we used practice summary data) and adjusted for minimisation factors.<sup>23</sup> We transformed CD4 count with a square root transformation and we log-transformed rate of diagnosis after adding 0.01 to zero counts. Using the intervention effect from the primary analysis and the normal distribution, we estimated the relative reduction in

percentage of patients with both CD4 count less than 350 cells per  $\mu\text{L}$  and CD4 less than 200 cells per  $\mu\text{L}$  with a method developed by Peacock and colleagues.<sup>24</sup>

Although we originally planned an as-treated secondary analysis excluding practices that had done less than 50 tests, this was not feasible because only four practices did more than 50 tests and no patients from these practices had been diagnosed with HIV.

The UK Antenatal HIV Screening Programme offers all women in antenatal care an HIV test. We did a pre-planned sensitivity analysis excluding women diagnosed via this programme. Some HIV-positive patients had previously been diagnosed but had defaulted from specialist care: re-diagnosis in general practice therefore led to re-entry to specialist care. We did a second sensitivity analysis including such patients.

This study is registered with ClinicalTrials.gov, number ISRCTN63473710.

### Role of the funding source

JF, a clinician employed by NHS City and Hackney, which funded the study, was involved in designing the study, data interpretation, and writing the report, but had no role in data collection or analysis. The Department of Health had no role in any aspect of the study. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

### Results

40 (89%) of 45 general practices agreed to take part (figure). The five practices that declined had similar characteristics to those that joined the study (data not shown). 20 practices were randomly assigned to intervention and 20 to control. Three practices in the intervention group withdrew during the study (one stopped offering registration health checks; one for workload reasons; and one closed), but all provided complete study data and were included in the intention-to-treat analyses. Practice and population characteristics and numbers of newly registering patients were well balanced at baseline (tables 1 and 2).

Baseline characteristics of study groups were similar for sex ( $p=0.742$ ), age ( $p=0.0413$ ), and ethnic origin ( $p=0.136$ ). Baseline characteristics for newly registered patients were much the same in each treatment group: number of new registrants ( $p=0.935$ ), sex ( $p=0.632$ ), age ( $p=0.416$ ), ethnic origin ( $p=0.136$ ), and age ( $p=0.416$ ).

Intervention practices offered 11 187 rapid tests, of which 4978 (45%) were accepted (table 3). Of these, 4964 were not reactive and 14 were reactive, including 11 that were confirmed HIV positive (true reactive) and three confirmed HIV negative (false reactive).

Overall, intervention practices identified 43 HIV-positive patients, of whom 11 had previously been diagnosed, giving a total of 32 new HIV diagnoses. Control practices identified 21 HIV-positive patients, of whom seven had previously been diagnosed, giving a total of 14 new HIV

	Intervention practices (n=20)	Control practices (n=20)
<b>General practices</b>		
List size		
<5000 patients	8 (40%)	8 (40%)
5000-7000 patients	5 (25%)	5 (25%)
$\geq 7000$ patients	7 (35%)	7 (35%)
HIV testing rate in men*		
<7	13 (65%)	13 (65%)
$\geq 7$	7 (35%)	7 (35%)
Index of multiple deprivation score		
<47	11 (55%)	10 (50%)
$\geq 47$	9 (45%)	10 (50%)
<b>Patients</b>		
Number of registered patients		
99 670		96 500
Age (years)		
16-24	15 623 (16%)	13 198 (14%)
25-34	28 200 (28%)	29 292 (30%)
35-49	31 218 (31%)	31 990 (33%)
$\geq 50$	24 629 (25%)	22 020 (23%)
Men	50 224 (50%)	48 929 (51%)
Ethnic origin		
White	40 250 (40%)	48 262 (50%)
Black	20 467 (21%)	17 690 (18%)
Asian	8487 (9%)	8002 (8%)
Mixed	3396 (3%)	4207 (4%)
Other	7134 (7%)	3562 (4%)
Unknown	19 936 (20%)	14 777 (15%)
Data are n (%). *Number of men tested April to October 2009/men registered $\times 1000$ .		

Table 1: Baseline characteristics

	Intervention practices (n=20)	Control practices (n=20)
Total number of new registrants	44 971	38 464
Median number of new registrants per practice (IQR)	1379 (943-3238)	1802 (952-2732)
Age (years)		
16-24	7667 (17%)	6207 (16%)
25-34	19 491 (43%)	18 170 (47%)
35-49	10 950 (24%)	9016 (23%)
≥50	6863 (15%)	5071 (13%)
Men	20 219 (45%)	17 119 (45%)
Ethnic origin		
White	23 947 (53%)	22 365 (58%)
Black	6400 (14%)	5253 (14%)
Asian	3472 (8%)	3011 (8%)
Mixed	1296 (3%)	1442 (4%)
Other	2066 (5%)	1389 (4%)
Unknown	7790 (17%)	5004 (13%)

Data are n (%) unless stated otherwise.

**Table 2: Characteristics of newly registered patients**

diagnoses (figure, table 3). The UK Antenatal Screening Programme led to three new HIV diagnoses in intervention practices, and four in control practices.

Of the 32 newly diagnosed patients in the intervention group, 19 (59%) were men, 20 (63%) were of black African origin, and six (16%) were men who have sex with men. Of the 14 patients diagnosed in control practices, eight (57%) were men, and ten (71%) were of black African origin, and none were men who have sex with men, although we had no data for sexual orientation for three men. No adverse event occurred during the study.

CD4 count was available for 30 of 32 newly diagnosed patients from intervention practices, and in all 14 patients from control practices. Mean CD4 count was not significantly different between intervention practices and control practices (356 cells per  $\mu\text{L}$  [SD 254] vs 270 cells per  $\mu\text{L}$  [SD 257]; adjusted difference in square root transformed CD4 count 3.1, 95% CI -1.2 to 7.4;  $p=0.16$ ; table 4). Mean CD4 count was significantly different when patients diagnosed via antenatal screening were excluded (6.4, 95% CI 1.2 to 11.6;  $p=0.017$ ; table 4), and when patients who had been previously diagnosed with HIV but defaulted from care were included in the analysis (4.1, 0.0 to 8.1;  $p=0.049$ ; table 4).

The rate of HIV diagnosis was 0.30 (95% CI 0.11 to 0.85) per 10000 patients per year in the intervention group and 0.07 (95% CI 0.02 to 0.20) in the control group (adjusted ratio of geometric means 4.51, 95% CI 1.27 to 16.05;  $p=0.021$ ). In a sensitivity analysis of newly diagnosed patients excluding those diagnosed during antenatal screening, the rate was 0.23 (95% CI 0.07 to 0.70) in the intervention group versus 0.04 (0.01 to 0.11) in the control group (adjusted ratio 5.88, 95% CI 1.71 to 20.17;  $p=0.006$ ). For all new diagnoses plus those

	Intervention practices (n=20)	Control practices (n=20)
<b>HIV testing</b>		
New registrants	44 971	38 464
Patients offered rapid tests	11 187	NA
Patients accepting rapid tests	4978	NA
Patients with unreactive rapid tests	4964	NA
Patients with reactive tests	14	NA
Patients confirmed HIV positive	11	NA
Patients tested by serology test*	2728	2465
<b>HIV diagnoses</b>		
Total (new and previously diagnosed)	43	21
New diagnoses	32	14
By rapid testing	11	NA
By opportunistic serology	18	10
In antenatal screening	3	4
Previously diagnosed	11	7
Defaulted from care	4	2
Retained in care	7	5
<b>Sensitivity analysis</b>		
New diagnoses excluding antenatal screening	29	10
All new diagnoses plus those defaulted from care	36	16

Data are n. \*Opportunistic testing, as part of antenatal screening, and confirmatory testing for rapid testing.

**Table 3: HIV testing and diagnoses**

defaulted from care, the rates were 0.32 (0.11 to 0.91) versus 0.07 (0.02 to 0.21; ratio 4.53, 95% CI 1.25 to 16.38;  $p=0.023$ ).

We estimated that 73% of patients in control practices had a CD4 count less than 350 cells per  $\mu\text{L}$ , compared with 55% of patients in intervention practices (risk ratio 0.75, 95% CI 0.53 to 1.07). 46% versus 28% had a CD4 count less than 200 cells per  $\mu\text{L}$  (risk ratio 0.60, 95% CI 0.32 to 1.13).

## Discussion

We have shown that an educational outreach programme promoting opt-out rapid HIV testing of people newly registering in general practice leads to increased rates of diagnosis of HIV. Our study did not show significant differences between groups in CD4 counts at diagnosis, although diagnosis seemed to be non-significantly earlier in the intervention clinics. These are key goals of HIV-focused clinical and public health programmes. The effect of rate of diagnosis was greater in sensitivity analyses excluding women diagnosed through the UK's existing antenatal HIV screening programme. Practices used both rapid and opportunistic serology testing to make new diagnoses. A high proportion of newly diagnosed patients were of black African ethnic origin, showing successful integration of testing into a multiethnic community, recognised as a hard-to-reach

	Intervention practices (n=20)			Control practices (n=20)			Difference (95% CI)*
	Number of patients	Mean CD4 count (SD; cells per $\mu$ L) <sup>†</sup>	Square root of mean CD4 count (SD)	Number of patients	Mean CD4 count (SD; cells per $\mu$ L)	Square root of mean CD4 count (SD)	
New diagnoses	32	356 (254)	17.7 (6.6)	14	270 (257)	14.7 (7.7)	3.1 (-1.2 to 7.4)
All new diagnoses excluding antenatal screening	29	369 (262)	18.0 (6.7)	10	194 (169)	12.4 (6.7)	6.4 (1.2 to 11.6)
All new diagnoses plus those defaulted from care	36	411 (288)	19.0 (7.2)	16	259 (242)	14.5 (7.3)	4.1 (0.0 to 8.1)

\*Calculated from square root of CD4 count and adjusted for minimisation factors. <sup>†</sup>CD4 cell count unavailable for two patients.

Table 4: CD4 cell count of newly diagnosed patients

population.<sup>25</sup> To our knowledge, this randomised trial is the first to show improvements in clinical outcomes from HIV screening.

Strengths of our study included a pragmatic real-world design that included almost all practices in the borough, improving the generalisability of our findings. Randomisation was robust, maintaining allocation concealment. Remote searching of practice computer systems ensured that data capture of testing activity and outcomes was consistent across practices. Access to test results from the regional laboratory ensured complete capture of all positive tests, minimising detection bias. The Public Health England national surveillance system enabled us to accurately distinguish between patients newly diagnosed in primary care from those who had previously tested positive. Validation of data extraction by an independent clinician, masked to allocation, of all newly diagnosed patients ensured accuracy and completeness of primary and secondary outcomes.

Our intervention was based on a successful screening intervention for tuberculosis in general practice,<sup>18</sup> which used various behaviour change techniques. Outreach visits, and clinician education combining mixed didactic and interactive elements, have been shown to be effective.<sup>26</sup> Computer prompts for testing and incentive fees might also have enhanced behaviour change.<sup>27</sup> A quality assurance scheme, which included competency-based training for rapid HIV testing, regular electronic monitoring of point-of-care results, and an assessment once every 2 months of staff using external control serum samples, enhanced patient safety by reducing the chances of incorrect rapid test results. All patients diagnosed by rapid testing were transferred to secondary care, showing that the links we established between general practice and specialist services were safe and effective. Some patients who had defaulted specialist care re-entered specialist services following a rediagnosis by their doctor, suggesting that primary care can play an important part in maintaining continuity of care.

A weakness of our study was that three intervention practices discontinued testing. These discontinuations are a consequence of the pragmatic study design. Nevertheless, we were able to include complete data from all practices in the analysis. Registration health checks are

optional, thus only patients that attend (about 50% of all registering patients) can be offered a test. Increasing attendance at checks would increase the effect of our intervention. Although we could not mask clinical and research teams to allocation, validation of data extraction by a masked independent clinician helped ensure the validity of the study data. Our analysis accounted for differences between practices in the total list. An additional factor that could be used is the consultation rate for adult patients for each practice. Our study was potentially underpowered: increasing attendance at registration health checks would increase the effect of our intervention.

Observational studies<sup>28</sup> suggest that targeted community-based approaches to HIV testing achieve high uptake and a higher proportion of patients with CD4 count of more than 350 cells per  $\mu$ L at diagnosis. In community centres in the USA, nurse-initiated routine universal non-targeted rapid HIV testing achieved similar uptake and numbers of new diagnoses to those in our study.<sup>29</sup> Nurse-initiated rapid testing with streamlined counselling in primary care is feasible compared with traditional approaches.<sup>29,30</sup> These findings lend credibility to our results.

Our findings provide firm evidence that HIV screening in primary care leads to increased and earlier HIV diagnosis. This finding addresses a key gap in the evidence base for HIV testing, lending strong evidence in support of guideline recommendations.

Our results justify renewed efforts to implement community screening for HIV. This study builds on previous work showing that opt-out screening for tuberculosis using a multifaceted educational intervention and valid implied consent is effective in primary care.<sup>18</sup> Screening for multiple infectious agents in at-risk populations therefore seems justifiable.

#### Contributors

CG had the original idea for the study. WL, HM, CG, JA, SC, DM, SM, JF, GH, RA, KB, SB, SK, ACS, FT-P, and MS designed the study. WL, HM, DM, SC, JA, and CG trained and educated general practice staff. WL, HM, and MS undertook the quality assurance. SK and NM did the statistical analyses. RA provided advice on ethical aspects of the trial, including data management and data protection. AM completed data quality assurance checks. VD, AB, and GR validated HIV diagnoses data. WL and CG wrote the first draft of the report with input from ACS, HM, JA, SK, SB, JF, AM, VD, and FT-P. All authors have seen and approved the final version of the report.

	Intervention practices (n=20)			Control practices (n=20)			Difference (95% CI)*
	Number of patients	Mean CD4 count (SD; cells per $\mu\text{L}$ ) <sup>†</sup>	Square root of mean CD4 count (SD)	Number of patients	Mean CD4 count (SD; cells per $\mu\text{L}$ )	Square root of mean CD4 count (SD)	
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**Data monitoring committee**

Claudia Estcourt, Karen Smith, Jill Zelin.

**Declaration of interests**

JA reports fees and non-financial support from Bristol-Myers Squibb, grants and personal fees from Gilead Sciences, personal fees from ViiV, personal fees from Merck Sharp & Dohme, grants from Janssen, and personal fees from AbbVie, outside the submitted work. The other authors declare no competing interests.

**Acknowledgments**

This study was funded by the UK Department of Health, and NHS City and Hackney. We thank all participants and general practices. We thank Keith Prescott, Arun Chinnaraj, Martin A Sharp, and Jack Dunne (Clinical Effectiveness Group, Queen Mary University of London, UK) for the extraction of demographic and HIV testing data. We are grateful to Damilola Awoosika for her assistance in collating data of newly diagnosed patients. Many thanks to Clare Rutterford for the practice randomisation and for doing quality checks on the final analysis.

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