# Title: Constructing a middle range theory to explain hepatitis C test uptake in prison

# Key words

Middle range theory, realist evaluation, hepatitis C virus, opt-out testing, prisons, incarceration

# Abstract

# Background

Prisons in England have a target to test 75% of those admitted for hepatitis C virus (HCV) infection. However, test uptake in the tax year 2018-2019 was 32.3%, (Public Health England, 2020), far below this goal.

# Aim

To present the process of constructing the *Middle Range Theories* (MRT) developed as part of an evaluation of hepatitis C test uptake in an English prison. MRT are propositions that can explain a particular behaviour or outcome.

# Discussion

In this paper, the MRT emerged from a realistic evaluation process, a theory driven approach developed by Pawson and Tilley (1997) to understanding what interventions work, in what circumstances and how. The mixed methods data collected during the realistic evaluation and the sociological theory *prisonization* were used to create the MRT. Combining the sociological theory of *prisonization* with the qualitative data illustrates how healthcare interventions may be viewed by people in prison who may have adopted either the deprivation or importation process of adaptation to cope with their incarceration. These views may impact on HCV test acceptance.

#### Conclusion

The development of MRT is a creative and iterative process, requiring an in-depth understanding of both the data collected and the subject area. Theories permit us to see relationships among phenomena that might otherwise seem disconnected, therefore aiding the development of more efficacious interventions.

#### Implications for practice

Realist methodology is an emerging approach in healthcare research and this paper is intended as a resource for researchers using this technique. The MRT developed presents an evidence base for selecting interventions to increase HCV uptake in prisons.

#### Introduction

The use of realist evaluation in health care sciences is increasing. The aim of this paper is to contribute to this discussion. It does this by exploring the process through which middle-range theory (MRT) is constructed using realistic evaluation methodology (Pawson & Tilley, 1997). Theories are important to realist evaluation as they form the means of providing plausible explanations of why certain interventions work or do not work in certain circumstances (Pawson & Tilley, 1997). In order to illustrate this concept of theory formulation the authors will draw on their own research and use of conducting a realistic evaluation when evaluating the impact of the opt-out hepatitis C virus (HCV) testing policy in English prisons (Jack, 2020a; Jack et al., 2020b; Jack et al., 2019).

#### Middle-range theory

Middle-range theory, developed by Robert K. Merton (1968), is an approach to sociological theorizing aimed at integrating theory with empirical research. A MRT, according to Merton (1968), consists of a set of assumptions from which a specific hypothesis is logically derived and subsequently confirmed by empirical investigation. Merton (1968: 39) defines MRTs as:

'that lie between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory that will explain all the observed uniformities of social behaviour, social organisation and social change'.

They do not seek to explain the whole in a single theory but seek to develop explanations for the parts that make up the whole, hence the term 'middle range'. MRT's have been used in nursing science to narrow the gap between nursing science theories and practice (Elo et al., 2013; Riegel et al., 2019) when exploring the complexities of an intervention or service.

#### **Realistic Evaluation**

As forerunners to realistic evaluation Chen & Rossi (1989) advocated theory driven evaluation. Theory driven evaluation focuses on the "black box", that is, the hidden space between an intervention and its outcome (Stame, 2004) whereby the researcher examines why and how a programme or intervention has worked. Theory-driven evaluation thus aims to access not only the effectiveness of an intervention but also its causal mechanisms, taking into account the context of the intervention.

Realistic evaluation can be considered as an approach within theory-driven evaluation and this is acknowledged within the work of the originators of *Realistic Evaluation*, Ray Pawson and Nick Tilley (1997). The Realistic Evaluation approach seeks to identify not just whether a programme has been successful, but *how* and *why* the programme outcomes are achieved. Realistic Evaluation asks; what works for whom in what circumstances (Pawson & Tilley, 1997: 220). Rather than seeking causation and generalisation as an end-product, as in succession theory, or the 'specification of the constructions held by the multiplicity of stakeholders' (Pawson and Tilley 1997: 118), to which constructivists are committed, a realist evaluator searches for 'cumulation' (Pawson and Tilley 1997: 119). By 'cumulation' they do not mean simply completing a series of studies with reliable evidence that can be applied universally, but the need to develop middle-range theories.

A key premise underlying realistic evaluation is that the concept of truth and falsity do not provide a coherent view of the relationship between knowledge and object. Rather, knowledge is a social and historical product, indeed Pawson and Tilley (1997: 65) contended that: 'A programme is its personnel, its place, its past and its prospects' and furthermore 'that it is not programmes which work, as such, but people cooperating and choosing to make them work '(Pawson & Tilley, 1997: 36). In this way, knowledge of facts gained from research do not simply speak for themselves and the task of science is to invent theories or explanations to explain the real world.

The choice of method open to the realist evaluator is pluralistic. Pawson and Tilley (1997) argued that it was perfectly possible to carry out realistic evaluation using a variety of data collection methods, but the selection should be made with reference to the proposed theories or explanations. Realistic evaluations follow a cyclical model, shown in Figure 1.



#### Figure 1: The Realist Evaluation Cycle (Pawson and Tilley, 1997:85)

Firstly, in the initial Theory stage, *programme theories* underpinning the intervention, or programme, of interest are constructed. A programme theory is simply the assumption(s) made by the programme designers that explains how, why and under what conditions they expect the intervention to work (Marchal et al., 2018: 83). The variety of possible contexts and mechanisms leading to the expected outcome are thus considered during this process. Mechanisms are the action or reaction to the intervention, or programme, that has been implemented, rather than the programme itself. During the second *Hypotheses* stage, the specific hypotheses deemed most plausible and able to explain the programme's outcomes are clarified. Existing published literature, clinical experience and programme outcome data

can aid the formation of programme theories, expressed as specific Context, Mechanism and Outcome configurations which are written as CMOc. Typically, the following questions would be addressed in the hypotheses: 1) what changes are outcomes that will be brought about by an intervention, 2) what contexts impinge on this, and 3) what mechanisms (social, cultural and others) would enable these changes, and which one may disable the intervention (Dobson, 2008). A mechanism explains what is responsible for the 'regularity' (Pawson and Tilley, 1997: 71) or outcomes found in the results of the study. The relationship between causal mechanisms and their effects is not fixed but contingent upon the context in which the mechanisms are activated (Sayer, 1984: 107). As Pawson (2002) argued, some programs may work for some people, for some of the time. The third step is the Observation stage whereby a mixed methods approach to data collection can fully explore the contexts and unseen domains of reality to consider what the mechanisms may be. In this stage it might be possible to provide evidence of the interventions ability to change reality. Based on the results obtained during the observation stage, we may return to the program (the intervention) to make it more specific as an intervention of practice. Next, but not finally, we return to the first theory stage. The research findings are analysed in conjunction with the original context-mechanism-outcome configurations that comprised the first programme theories and evidence sought to substantiate or refute the theories. The theories may be further developed, the hypotheses refined, or the data collection methods altered. This process of refining the original programme theories is again articulated and illustrated in the formation of new context-mechanism-outcome configurations.

Realistic explanation, therefore, is based on the proposition that causal outcomes follow from mechanisms acting in contexts. A realist evaluation (RE) cycle involves framing theories which identify and explain regularities, deriving hypotheses concerning what might work for whom in what circumstances, testing these through multi-method data collection and analysis, which can then inform further generalisations and lead to revision of theory and new hypotheses. Thus, we begin by expecting measures to vary in their impact depending on the conditions in which they are induced and actions.

#### Limitations of realistic evaluation

Realistic evaluation, as with all research methodologies, is subject to limitations. Whilst the process of identifying unseen causal mechanisms offers advantages over the randomised controlled trials that form the mainstay of evidence based practice, the predictive claims are less robust (Porter & O'Halloran, 2012). Mechanisms are theories of human actions and reactions, so it is possible that the choice of mechanism to be included in a CMOc is heavily influenced by the researcher and thus may not be the most applicable in the situation under investigation (Kazi, 2000: 164). This can be a particular risk when the researcher is identifying mechanisms influenced by their own clinical experiences and presuppositions. Furthermore, when the mechanisms have been identified by the service users, their relationships with the staff may shape the actions and reactions revealed to the researcher (Kazi, 2000: 164). For example in the MRT development presented in this paper, the power relations between the people in prison (PIP) and both the custodial and healthcare staff, in addition to the restrictive prison context, may have consciously or unconsciously influenced the mechanisms expressed during the qualitative interviews that underpinned this MRT development (Jack et al., 2020)

#### The development of a middle-range theory in a realistic evaluation cycle

To begin evaluating a programme using the principles of realistic evaluation, the researcher frames theories in terms of propositions about how the mechanisms are triggered. Pawson and Tilley (1997: 88) called such theories, 'folk theories' suggesting that they develop from people's experiences. These are developed further analysing the data derived from the chosen methodology, which may be quantitative or qualitative or both. Each CMO forms the basis of a 'mini-experiment'. Through a measurement of a series of CMOs it should be possible to deduce the features of contexts that allow different mechanisms to work to achieve particular outcomes. Thus, 'transferable lessons' may be learned (Pawson & Tilley 1997: 90), accumulating in a middle-range theory to explain the phenomena under investigation.

Complex interventions are characterised by multiple parts which interact with each other and the political, historical, social and geographic contexts in which they are situated to produce outcomes (Clark, 2013). Prison health care services can be described by their very nature as being complex. There is a higher prevalence of HCV among people in prison (PIP) versus the community; 7% versus <1% respectively (Public Health England, 2014) and 8% versus 2% respectively (Public Health England, 2015). Therefore a national policy to increase testing from 7.8% to over 75% using an opt-out approach was introduced in 2014. However test uptake had increased to only 19% by 2017/2018. Public Health England theorised that an opt-out approach to HCV testing in prisons would increase test uptake (*outcome*) on the grounds that firstly, this approach works in antenatal and GUM clinical settings (*context*) and secondly, it will reduce stigma by testing everyone and not singling out individuals (*mechanism*) (NHS England, 2013; NHS Executive, 1999; Public Health England, 2017).

The quantative and qualitative data that were collected during the observation phase of the RE cycle (Jack, 2020a; Jack et al., 2020b; Jack et al., 2019) and existing literature informed the Initial PT which were refined. During the final stage of the RE cycle, where researchers return to the original theory stage and construct a MRT, the authors iteratively debated the existing literature, the emergent qualitative themes of Fear, Insufficient Knowledge, Stigma, Privacy, Choice, Prison Life, Test Uptake Facilitators and Health Farm from the data collected in the current *research* (Jack et al., 2020b) and the refined programme theories. These were reviewed along with the pre-existing sociological theories of prisonization (explained briefly in the next section of this paper) about how people adapt to being in prison. The authors' experiences and observations about delivering healthcare in prisons further influenced the MRTs. Specifically, prison nursing activity occurs in a context that is completely alien to the majority of healthcare professionals (Norman & Parrish, 1999). This can lead to unrealistic expectations by external policy-makers of what is feasible for nurses to achieve given the constraints of competing clinical priorities and the prison security regime. It was thus considered essential by the authors that the context of delivering nursing care inside a prison should feature prominently in the emergent MRTs.

#### Prisonization

The theory of *prisonization* was initiated by Clemmer (1940), who observed the prison environment and noted the adaptation people make when adjusting to life in prison. Clemmer described prisons as *"a self-contained world that is vastly different from the rest of society"* (Krebs, 2002). *Prisonization* encapsulates the way in which those who are imprisoned absorb the "folkways, mores, customs and general culture of the penitentiary" (Clemmer, 1940). The mechanism of accepting and negotiating prison life involves

adherence to the "inmates code", described as a contra-culture whereby loyalty is directed to other people in prison (PIP) rather than prison staff (Akers et al., 1977). This leads to oppositional behaviour where the prison's rules and values are rejected and a commitment to values and behaviours beyond conventional society is reinforced (Drake et al., 2015). Sykes (1958) advanced this initial theory by positing that prisons exerted "pains" of imprisonment which altered the relationships between people, requiring adaptive behaviour in order to cope with prison life. These pains were the deprivation of "liberty, goods and services, heterosexual relationships, autonomy and security" and resulted in covert, sometimes illegal, activities and a competitive PIP hierarchy. Irwin & Cressey (1962) challenged Sykes' view that *deprivation* explained the PIP's adaptive behaviour on the grounds that it was not just the prison environment that affected their assimilation into the secure environment but the values and behaviours *imported* by the PIP too. Thus Irwin & Cressey (1962) argued that people's social roles, subcultures and psycho-social environment prior to entering prison would determine their behaviour.

The *prisonization* theory is woven into the process of *realistic cumulation* and development of a MRT, still expressed as a CMOc, defined as being "abstract enough to underpin the development of a range of programme types yet concrete enough to withstand testing in the details of a (further) programme implementation" (Pawson & Tilley, 1997: 116). A MRT of barriers and facilitators to engaging in the BBV test and treat pathway, expressed as three CMOc which focus on the sociological *deprivation* and *importation* theories and prison context has been developed. This MRT is constructed to explain HCV test uptake from the PIP's perspective and forms a model on which interventions aimed at specifically harnessing the facilitators and reducing the barriers are suggested. The model may appear to contain

generalisations but this is an inevitable consequence of an overarching theory designed to apply or be tested across the entire prison estate in England. The MRT is explained in the following three tables and commentary.

# Table 1: Middle Range Theory (1): Deprivation

CONTEXT	MECHANISM	OUTCOME	INTERVENTIONS
Deprivation model of prisonization	$M_{1a}$ Fear of social isolation if identified as HCV positive or as a PWID	O <sub>1a/b</sub> PIP may prioritise their privacy over health	Increase availability of testing: <ul> <li>multiple staff</li> <li>range of locations</li> </ul>
	M <sub>1b</sub> Fear of further stigma if identified as HCV positive or as a PWID		<ul> <li>variety of time points</li> <li>adding BBV testing to existing interventions</li> </ul>
	M <sub>2a</sub> Inability to access healthcare due to inadequate numbers of prison officers	O <sub>2a</sub> PIP unable to access testing due to security regime prioritised over health	
	M <sub>2b</sub> Inability to access healthcare department due to bullying	O <sub>2b</sub> PIP may refuse to attend appointments in the healthcare department	Enable rapid instigation of treatment to reduce window of opportunity for potential identification of status
	M <sub>3a</sub> PIP have a lack of control in prison but exercise their right to choose healthcare	O₃a Choice is more important than non- urgent healthcare	Discuss facilitation of HCV micro- elimination with prison Governors e.g. • reward participation in BBV testing • increase unlock time to facilitate
	$M_{3b}$ Oppositional behaviour exhibited by PIP to regain control	$O_{3b}$ PIP choose not to engage in HCV testing	<ul> <li>testing</li> <li>clean injecting equipment provided on liberation</li> </ul>
	M <sub>4a</sub> Fear of catching HCV infection in prison	$O_{4a/b}$ PIP are keen to be tested (and treated) for reassurance they are leaving prison healthy	<ul> <li>increase prison officers knowledge to promote normality</li> <li>PIP self-testing with DBS</li> </ul>
	M <sub>4b</sub> Fear of taking HCV infection home to family		
			Explain routes of HCV transmission in prisons to PIP, prison staff and nurses
Deprived of liberty, usual social relationships and choice	Qualitative Themes: <i>privacy, stigma, fear, choice, prison life</i>		Test Uptake Facilitators: <i>Flexible and creative service delivery</i>

CONTEXT	MECHANISM	OUTCOME	INTERVENTIONS
CONTEXT Importation model of prisonization	MECHANISM         M1 PIP with HCV infection bring pre- existing felt and enacted stigma into prison         M2 PIP with an IDU history who know they are at a high risk of being infected         M3 PIP bring pre-existing beliefs and knowledge about HCV into prison which	OUTCOME         O1 PIP do not wish to be identified as infected and risk social isolation and further stigma         O2 PIP may have risk factors but they may not wish to be identified as infected with HCV or as a PWID and risk stigma and social exclusion         O3 PIP feel that BBV testing does not	INTERVENTIONS Increase awareness of HCV in the general population Increase variety and visibility of HCV awareness materials, replacing as soon as damaged e.g. information in "first night" packs electronic reminders on wings posters in multiple locations peer support
	May or may not be accurate M4 PIP enter prison with stress and anxiety, drug or alcohol withdrawal or acute presentation of an enduring psychiatric illness	<ul> <li>apply to them because they are not at risk</li> <li>O<sub>4a</sub> PIP refuse to be tested as they do not feel emotionally able to cope with a positive diagnosis</li> <li>O<sub>4b</sub> Nurses make a clinical judgment not to test due to competing health priorities</li> </ul>	<ul> <li>peer support</li> <li>prison radio/TV</li> <li>Increase training and support for nurses to operate opt-out testing</li> <li>Continue to offer testing on arrival, but actively follow up those who decline or in whom it is clinically inappropriate to discuss on arrival</li> </ul>
	M₅ PIP who know or suspect they are infected with HCV and are keen to engage with prison healthcare	O <sub>5</sub> PIP accept test when offered or actively seek a test in prison	Explain routes of HCV transmission in prisons Explore reasons for test decline
Pre-prison knowledge, beliefs and experiences	Qualitative Themes: stigma, fear knowledge, prison life, health farm		Test Uptake Facilitators: Education

# Table 2: Middle Range Theory (2): Importation

CONTEXT	MECHANISM	OUTCOME	INTERVENTION
Nursing in prison	M <sub>1a</sub> Competing clinical demands on nurses' time	O <sub>1a</sub> no time / space during reception	Specialist nurses and hospital managers to spend time with prison nurses and managers to forge a supportive
	<ul> <li>M<sub>1b</sub> Conflict between health and security demands on time</li> <li>M<sub>2a</sub> Prison regime prioritised over proactive healthcare so nurses do not</li> </ul>	O <sub>1b</sub> inability to choose how and when to implement BBV testing O <sub>2a/b</sub> Nurses have reduced control of healthcare delivery	partnership Provide educational opportunities for prison nurses and HCAs
	have free access to people M <sub>2b</sub> Nurse access to PIP is contingent upon sufficient prison officers		Introduce a standard opt-out script: "We test everyone who comes into prison for hepatitis C (which is completely curable), hepatitis B and HIV (which are
	M <sub>3a</sub> Prison nurses have different clinical experiences and perspectives to hospital hepatitis / liver nurses	O <sub>3a</sub> Prison nurses have insufficient understanding about individual and public health consequences of HCV infection O <sub>3b</sub> Prison nurses have insufficient	treatable), is that OK with you?"
	M <sub>3b</sub> Prison nurses need on-going support to deliver opt-out testing	understanding about the delivery of opt- out testing	
Prisons	Qualitative Themes: knowledge, prison life		Test Uptake Facilitators: Hospital nurses to increase support to prison nurses

# Table 3: Middle Range Theory (3): Nursing in Prison

The first CMOc of the MRT focusses on the *deprivation* theory to explain prisonization (Table 1). Deprived of liberty, usual social relationships and choice, mechanisms identified within the qualitative themes of *Privacy, Stigma, Fear, Choice* and *Prison life* lead to both avoidance of and a keen interest in HCV testing. The desire expressed by many PIP to leave prison healthy without an infection that could be transmitted to loved ones is a feature that could be capitalised on. Suggested interventions to increase test uptake are framed by the notion of flexible and creative service delivery that may benefit health without compromising prison safety and security.

The second CMOc of the MRT is directed towards the *importation* theory of prisonization (Table 2). In this scenario, pre-existing knowledge, beliefs and experiences that PIP bring into prison with them form the context. Mechanisms identified within the qualitative themes of *Stigma, Fear, Knowledge, and Prison Life* result in poor HCV test uptake due to anxiety, lack of knowledge or it being clinically inappropriate. However, some PIP actively seek to engage in healthcare in prison as identified in the *Health Farm* theme because their pre-prison experiences reduce opportunity for healthcare engagement. Potential interventions that address PIP behaviours in this model are centred on education, not just to the PIP but to the wider population so that awareness of HCV is increased before people enter prison. Furthermore, local and national strategic decision makers would benefit from further education about why PIP are not able to undergo or decline HCV testing.

Both of these MRT models are situated in an overarching context of the non-negotiable requirement to maintain prison safety and security. This leads inevitably to health care professionals not having the same freedom to plan and deliver care that staff in any other

context most likely take for granted. The third CMOc of the MRT (Table 3) attends specifically to the prison context and its impact on HCV testing. Mechanisms uncovered in the qualitative themes *knowledge* and *prison life* confirm that non-emergency prison healthcare is contingent upon access controlled by the prison regime. Furthermore, prison staff nurses by the nature of their role are not specialists in blood borne virus management so will have less awareness of all the details of the HCV test and treatment pathways. The exclusion to date of prison nurses in national or local educational opportunities, whilst not deliberate, contributes to a lack of proactive engagement in delivering the opt-out testing strategy. Therefore, it is important for hospital specialists to promote increased partnerships, a mutual understanding of each other's environments and challenges, and share knowledge.

### Conclusion

The realistic evaluation goal is to seek a robust transferable 'theory' as opposed to generalizable result (Emmel et al., 2018: 7). Whilst programme theories, expressed as CMOc, are assumptions about how and why an intervention is performing, a MRT provides a formal link between research and interventions (Marchal et al., 2018: 84). In this way, effectiveness of the programme is apprehended with an explanation of why the outcomes developed as they did, and how the programme was able to react to the other underlying mechanisms, and in what contexts. This analysis provides not only evidence of effectiveness, but also an explanation that helps to develop and to improve both the content and the targeting of future programmes.

#### Abbreviations

PT Programme Theory CMOc Context-Mechanism-Outcome configuration MRT Middle Range Theory RE Realistic Evaluation HCV Hepatitis C Virus PIP People in Prison

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