health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine

DOI: 10.1177/1363459307080876
Vol 11(4): 513–539

A critical realist approach to understanding and evaluating heart health programmes

Alexander M. Clark, Paul D. MacIntyre & Justin Cruickshank

University of Alberta, Edmonton, Canada, & University of Birmingham, UK, University of Glasgow, UK

ABSTRACT Secondary prevention programmes for Coronary Heart Disease (CHD) aim to reduce cardiovascular risks and promote health in people with heart disease. Though programmes have been associated with health improvements in study populations, access to programmes remains low, and quality and effectiveness is highly variable. Current guidelines propose significant modifications to programmes, but existing research provides little insight into why programme effectiveness varies so much. Drawing on a critical realist approach, this article argues that current research has been based on an impoverished ontology, which has elements of positivism, does not explore the social determinants of health or the effects on outcomes of salient contextual factors, and thereby fails to account for programme variations. Alternative constructivist approaches are also weak and lacking in clinical credibility. An alternative critical realist approach is proposed that draws on the merits of subjectivist and objectivist approaches but also reflects the complex interplay between individual, programme-related, socio-cultural and organizational factors that influence health outcomes in open systems. This approach embraces measurement of objective effectiveness but also examines the mechanisms, organizational and contextual-related factors causing these outcomes. Finally, a practical example of how a critical realist approach can guide research into secondary prevention programmes is provided.

KEYWORDS *cardiac; evaluation; heart; philosophy; prevention; rehabilitation*

ADDRESS Alexander Clark, 3rd Floor Clinical Sciences Building, University of Alberta, Edmonton Alberta, T6G 2G3, Canada. [Tel: +1 780 492 8347; fax: +1 780 492 2551; e-mail: Alex.clark@ualberta.ca]

ACKNOWLEDGEMENTS Thanks are given to the Scottish Executive National Demonstration Project 'Have a Heart Paisley' (HaHP) and the research and practice contributors to the various studies of the HaHP evaluation.

AMC is supported as an Alberta Heritage Population Health Investigator and Canadian Institutes of Health Research New Investigator.

Background

Cardiac rehabilitation is offered throughout the developed world to people with coronary heart disease (CHD) and is the: 'sum of activities required to influence favourably the underlying cause of disease, as well as to ensure the patients the best possible physical, mental and social conditions …' (World Health Organization, 1993: 5). There is a large evidence-base supporting the effectiveness of these activities either through hospital-based or community-based programmes (McAlister et al., 2001a; De Backer et al., 2003; Clark et al., 2005b). These services, collectively known as secondary prevention programmes, focus on promoting physical activity, healthy diet and body weight, smoking cessation and psycho-social well-being (Balady et al.,2000; Linden, 2000; SIGN Guidelines Network, 2000; Jolliffe et al., 2001; Leon et al., 2005).

Across Europe and North America, in-hospital rehabilitation usually commences in earnest four to six weeks after hospital discharge when patients are invited to attend centralized sessions with other patients. These sessions are offered over six to 12 weeks and contain health education support, supervised exercise sessions and behavioural change interventions (Bethell et al., 2001). More recently, similar services have also been offered in the community (most often in general practice) using an individual 'clinic'-type model. In both guises, programmes are multidisciplinary, co-ordinated and staffed predominantly by nurses with additional input from physiotherapists, general physicians, cardiologists, occupational therapists, dieticians and psychologists (Horgan et al., 1992; Davidson et al., 1995; Thompson and Bowman, 1995; Lewin et al., 1998; Bethell, 2000).

Poor outcomes, access issues and inequalities

The number of providers of these programmes is substantial and has grown markedly over the last 30 years. There are 200–500 cardiac rehabilitation programmes alone in North America, Europe and Australasia (Thomas et al., 1996; Bethell, 2000; National Heart Foundation of Australia, 2001). Despite the potential benefits of healthier behaviours in patients with CHD, a wealth of research has identified that uptake and attendance at in-hospital programmes remains around 30 per cent for eligible patients (Thomas et al., 1996; NHS Centre for Reviews and Dissemination, 1998; Bethell et al., 2001). Women, ethnic minorities, the elderly and those on lower incomes, are consistently noted as being less likely to participate (Cooper et al., 1999; Beswick et al., 2004).

Evaluation of services and current research

Evaluation of programmes has thus far sought to establish effectiveness of these interventions (Thompson, 2002). A wealth of pre- and post-test studies have demonstrated that the discrete components of programmes (such as smoking cessation), considered individually, can improve health

outcomes in men and women irrespective of age (Wenger et al., 1995; Ades et al., 1999). However, it is less certain what added value is gained from combining the components into one service package (Thompson, 2002).

Meta-analyses of existing trials report that programmes can significantly improve mortality, morbidity and quality of life (Oldridge et al., 1988; Bobbio, 1989; O'Conner et al., 1989; Linden, 2000; Jolliffe et al., 2001; McAlister et al., 2001a; Clark et al., 2005d). These meta-analyses show combined reductions in all-cause mortality of between 9 and 32 per cent. Of course, these analyses include some of the same trials, but confidence in this effect accrues from the large size of the population that these trends are derived from and the relative homogeneity of patients included (Table 1, column 3). The 'take home' message that programmes save and improve lives (Table 1, column 6) accords with the stoical observation of Pawson and Tilley (1997): that 'everything' seems to work.

However, this ignores the substantial variability across trial results (Table 1, column 5). For example, 15 to 70 per cent of studies included in each meta-analysis found no benefits in the raw data. Few explanations are offered to explain the lack of consistency between the trials. As 'grand summaries of summaries', meta-analyses are prone to filtering out variations in effectiveness and even basic programme characteristics or contexts (Clark et al., 2005d). Moreover, the original studies shed little light on which components are most influential, or how particular programmes/setting characteristics influence outcomes (Clark et al., 2005b). As such, even though programmes are proposed as making the difference, there is little current knowledge of what characteristics influence effectiveness, the influence of context or the mechanisms of effect of programmes.

Are programmes the same as pharmacological agents?

Evaluation has used the randomized control trial (RCT) to progress from the search for regularity, to propose that programmes unequivocally yield positive outcomes. The assumption is that programmes *themselves* have the power to affect positive change regardless of context or patient characteristics. Hence, the meta-analyses discuss effectiveness as being programme-determined and applying across populations irrespective of sex, age, disease, cultural and socioeconomic differences.

The approach used in current research is akin to that used when evaluating pharmaceutical treatments (see Figure 1). This approach conceptualizes a programme as a homogeneous and fixed intervention that is applied to passive and decontextualized individuals. Using this approach, effectiveness is about differences in key measurements (m) before and after the programme (mB to mA). In an RCT, this approach does little to account for the inconsistencies in outcome and access between programmes (what happens between mB and mA). It does not explore how a programme's parties (patients or professionals), organization and context influence

Table 1 **Results from meta-analyses of secondary prevention programmes**

Review	*Type of intervention*	*No. of patients / No. of trials/pt diagnosis(es)*	*Synthesized findings of reductions in all cause mortality*	*Proportion of studies demonstrating* ***no therapeutic effect*** *on all cause mortality*	*Take 'home' message taken directly from article*
Oldridge et al. (1988)	Cardiac Rehabilitation (Exercise & Comprehensive)	4347 / 10 / MI	24 % reduction (95% CI 0.63 to 0.92)	2/9	'Comprehensive cardiac rehabilitation has a beneficial effect on mortality but not on nonfatal recurrent myocardial infarction'
Bobbio (1989)	Cardiac Rehabilitation (Exercise)	2260 / 8 / MI	32% reduction (95% CI 0.53 to 0.86)	2/8	'The results show a highly favorable reduction in both total mortality and in cardiac deaths in treated patients…'
O' Conner et al. (1989)	Cardiac Rehabilitation (Exercise)	4554 / 22 / MI	20% reduction (95% CI 0.66 to 0.96)	9/22 (>3 years)	'Reduced risks of cardiovascular mortality and fatal infarction persists for at least 3 years after infarction'
Jolliffe et al. (2001)	Cardiac Rehabilitation (Exercise & Comprehensive)	8440 / 29 / MI, Coronary Artery Bypass, angioplasty, angina	27% reduction (95% CI 0.54 to 0.98) (Exercise) 13% reduction (95% CI 0.71 to 1.05) (Comprehensive)	5/12 (EO) 15/29 (CCR)	'…either form of cardiac rehabilitation can reduce the likelihood of dying from heart disease'
McAlister et al. (2001b)	Cardiac Rehabilitation & Secondary Prevention Programmes (Comprehensive)	9803 / 12 / MI, angina, Coronary Artery Bypass, angioplasty	9% reduction (95% CI 0.79 to 1.04)	7/10 (containing survival benefit data)	'Disease management programmes improve processes of care, reduce admissions to hospital and enhance quality of life or functional status of patients with CHD'
Clark et al. (2005b, 2005d)	Cardiac Rehabilitation & Secondary Prevention Programmes (Exercise & Comprehensive)	18842 / 41 / MI, angina, Coronary Artery Bypass, angioplasty	14% reduction (95% CI .72 to 1.03) (Comprehensive) 28% reduction (95% CI 0.54 to 0.95) (Exercise)	5/14 (CCR) 6/13 (Ind) 2/13 (EO)	'A wide variety of secondary prevention programs improve health outcomes in patients with coronary disease'

Note: CCR = Comprehensive Cardiac Rehabilitation Ind = Individual Counselling EO = Executive Only

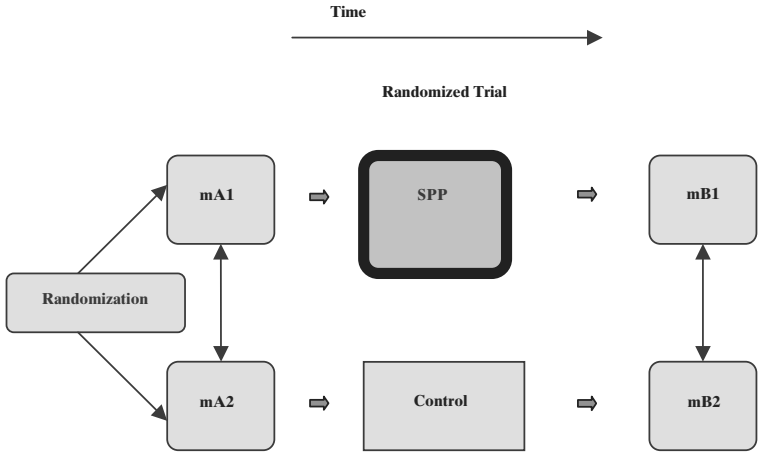

Figure 1 **Evaluating a secondary prevention programme: using the randomized trial**

outcomes or examine how dimensions of programmes actually lead to changes in patients (Pawson and Tilley, 1997).

These issues could be seen as methodological as opposed to philosophical. However, methods are imbued with all manner of philosophical tenets and ontological positions; that is, they must take implicit positions on what reality is, how it can be known and what ways are acceptable to do this (Paley, 1998, 2005). Focusing on this deep level, the labelling of approaches, studies or people as 'positivist' is an often mis-used criticism that builds a straw man based on a mixture of misconception and stereotype (Clark, 1998; Paley, 2005). However, the approach used towards the prevention programmes in this instance reflects core positivist assumptions in its lack of focus on unobservable phenomena, its impoverished conception of the social, contextual and personal and its reliance on a narrow body of empirical evidence (Table 2).

Evidence for the neglect of these dimensions is apparent in existing literature. In terms of the individual, most of the main outcomes of programmes manifest in the individual 'patient', for example: attendance levels, survival rates, rehospitalization rates and behavioural changes (see, for example, the clinical guidelines of Department of Health (2000) and SIGN (2002); and recommended national minimum data sets (University of York, 2005)). Guidelines and programmes tend to ascribe high status to human agency in determining health behaviours. Some programmes operate under the implicit or explicit assumption that, to change behaviour, individuals predominantly need information on heart health risks, the benefits of exercise, smoking cessation and a low-fat diet (see Farrant and Russell, 1986; Clark et al., 2002). This reflects discourse common in public health, medical psychology and some

variations of anthropology (Petersen and Lupton, 1996) that posits individuals as rational decision-makers who can process and act on risks irrespective of context. This perspective assumes that patients will logically choose healthy behaviours when presented with the right information (Farrant and Russell, 1986; Clark et al., 2002; Dein, 2003)

Yet ironically, despite the supposed primacy of the individual, the perspectives of individual users are neglected in the vast majority of research. Little research has explored individuals' experiences of programmes or examined how programme dimensions lead to changes in behaviours. There are a few notable and useful exceptions to this, which collectively convey that individuals do not experience programmes as blank sheets but bring lay epidemiology, fears and preferences which influence behaviour (Murray, 1989; Thompson et al., 1995; Fridlund, 1997; Wiles, 1998; McSweeney and Crane, 2001; Tod et al., 2002). Agency is therefore most often acknowledged with regard to biology and behavioural change, whereas individuals' meanings, experiences and reactions to the programme and the effects of their wider context are simultaneously disregarded.

Contradictory perspectives are also evident vis-à-vis the power of structural factors to facilitate individual change. Discourse here is around '*programme* effectiveness' (SIGN, 2000; Third joint task force of European and other societies on cardiovascular disease prevention in clinical practice, 2003; Clark et al., 2005d) with little reference or qualification being made to other factors (Table 1, column 6). Yet, programmes are grounded in well-established pre-existing organizational, social and cultural contexts (Pawson and Tilley, 1997). Organizational contexts are likely to affect the content/perception of and reactions to programmes. After programme completion, contextual factors will impinge on willingness and capacity to make health behaviour changes in the community (Wilkinson and Marmot, 2003). Individuals living in adverse social circumstances are more prone to negative health effects due to factors such as: psychological stress, poor housing, poor transport, insecure work, low social cohesion and social exclusion. For example, the places where people live influence their health and health opportunities (Macintyre et al., 2002). Cigarette smoking can be more common, socially acceptable and cheaper in some settings than others (Stead et al., 2001; Wiltshire et al., 2001). The nature of smoking cessation for people living in these different settings is considerably different.

Such structural factors, though known internationally to impact upon health, are seldom acknowledged in the secondary prevention/rehabilitation literature. This neglect is glaring considering that synthesis of outcomes suggests that reductions in cardiovascular risk will only occur with sustained behavioural change two to five years after attendance at programmes (Clark et al., 2005b); that is, when participants are well established in their communities.

Once more, programmes are ascribed primary power to instigate changes in outcomes; in this case, to the neglect of other determinants of health,

including organizational and social contexts. On the one hand, the presence of the programme as a structural entity affecting participants is seen as being the principal determinant of health improvement, yet programmes are arbitrarily ascribed disproportionate power in facilitating this in comparison to other structural factors known to impact on health.

The hermeneutical-individualist view

A commonly invoked alternative to the positivist approach is the hermeneutical-individualist approach, which is based on constructivism (Sayer, 2000). Variations of constructivism are common in nursing, medical sociology and qualitative research movements as an alternative to positivist approaches (Sayer, 2000; Williams, 2003). This approach clearly writes the individual back in (See Table 2).

There is good evidence that people's experiences and views of their body, self, other patients and health professionals influence decisions to participate in secondary prevention programmes (Wiles, 1998; Tod et al., 2002). Moreover, a wealth of evidence and theory suggests that these and similar individual cognitive and motivational factors influence behavioural change (Prochaska and DiClemente, 1982) and can be harnessed to develop interventions (Riemsma et al., 2003).

At a more extreme level, this view places primacy on the individual's mind in determining the world and can question the validity and existence of objective knowledge (Williams, 1999; Paley, 2005). The reality of such concepts is questioned as they are seen to be power-invoked social constructs without any independent reality (Williams, 1999; Crossley, 2004).

This view conflicts with health disciplines that, by nature, seek to eradicate pathogens and injuries that have a reality beyond individuals' beliefs, hopes and perceptions (Williams, 2003). It also contradicts the quest of the public health movement to mitigate the negative effects on health of the web of real social and cultural factors. Implicit then in health disciplines is the assumption that reality is not mind-dependent and that disease or health states have independent existences that, in some cases, can be objectively modified (Kikuchi and Simmons, 1996).

The importance of these assumptions was demonstrated in the struggles of a heart-health evaluation that, in reaction to positivism, attempted to utilize a hermeneutical/constructivist approach. Nguyen and Otis (2003) worked with a primary prevention heart health intervention in Montreal, Canada. The intervention involved mailing of information to the community on heart disease, school programmes, physical activity and walking club sessions for adults and children, community risk factor screening and political lobbying for bicycle paths. The authors report that the original evaluation of the programme was purportedly 'positivist' in orientation because it measured impact of the intervention on beliefs, attitudes, norms and skills; the availability of health opportunities (such as low-fat food and non-smoking areas), reactions in target populations and programme

Table 2 **Approaches to understanding secondary prevention programmes**

	Positivistic approach	*Hermeneutical approach*	*Critical realist approach*
Ontology	Flat; often under-theorized	Discourse-based, lack of commitment to universal of wider truths	Stratified ontology that draws a distinction between (1) experiences, (2) events/outcomes and (3) deep structures that exert a real power over (2) outcomes[a]
Causality	Successionist	Discourse-based	Generative
Description of cardiac rehabilitation	Strong focus on 'hard' outcomes such as mortality and morbidity; some focus on class of intervention; little focus or power attributed to programme characteristics, contexts or populations	Primacy given to the individual's experience of intervention; struggles to account for objective truths, and scientific evidence for risk factors or programme effectiveness	Recognizes the importance of measuring 'hard outcomes' and social determinants of health but also of explaining variations in outcomes and mediating mechanisms in different patients and groups. Views effect of intervention as subjective through the action of mechanisms but linked to objective programme characteristics
Agency	Health status determined by individual personal risk factors but little focus on the perspectives of the individual[b]	Strong sense of agency in terms of hermeneutics to the exclusion or neglect of other factors Little examination across populations for similar reactions to similar programmes or reactions to contextual factors	Acknowledgement of the power of individual agency to instigate change but also cognizant of the constrained and embedded nature of this agency
Structure	Arguably very structuralist, given the attribution of power ascribed to programmes in instigating change.[c] Lacks recognition of the role of context in influencing health outcomes; or posits that all contextual factors can be controlled	Limited acknowledgement due to focus on hermeneutical dimensions of agency Little weight given to structuralist factors in determining programme outcomes	Recognition that programmes and contexts will both support and constrain agency factors

Emancipatory	Views programmes as having the power to influence individuals[d]	Views individuals as reacting to experiences of programmes but limits programme capacity and context to influence change in groups of individuals	Individuals have power to change personal health behaviours but only at certain times, in certain contexts when the right mechanisms are activated
Strengths	Recognizes that programmes have effects on real and important entities, such as cardiovascular risk Generates knowledge of what does and does not work for specific populations or demographic groups	Recognizes that personal beliefs and meanings influence health change Recognizes the social and cultural discourses present in populations	Recognizes that health outcomes are determined by both agency and structural factors and that the interaction of these factors is complex Generates knowledge of what works for whom, when and why
Weaknesses	Attempts to control for or fails to acknowledge contextual and personal factors affecting outcomes No explanation of variations in effectiveness within and between programmes Denies human experience on the individual level as influential to outcomes	Potentially at philosophical odds with health care as a practical, emancipatory and evidence-based endeavour[e] Struggles to recognize the objective reality of cardiovascular risk factors, health inequalities or socio-biological pathways, while denying hegemonic structural forces	How can researchers identify and provide a case for the existence and power of mechanisms? Since contexts vary indefinitely, how can effective programme models be easily adapted to different settings?

[a] See Archer (1995) for a comprehensive overview of the agency–structure debate and realism's attempts to resolve this in social science.
[b] See Pawson and Tilley (1997) for a discussion of the paradoxical manner in which evaluators tend to measure programme outcomes in the individual but so readily turn away from the individual.
[c,d] See Table 1, column 6: cardiac rehabilitation programmes are often presented in terms of the efficacy of programmes or the relative efficacy of different *classes* of programmes. When combined with a lack of research on what individual factors are changed by programmes, this suggests that programmes can be health improving but with such a strong determinism that the individual and their context is effectively written out.
[e] If discourse is all, what then for the diseased cancer patient who is in denial or the health professional who is seeking a treatment for their cancer? See Kikuchi and Simmons (1996) for a consideration of the importance of truth in health care research and practice.

penetration. However, this evaluation plan was heavily criticized locally for its preoccupation with individual behaviour, reliance on a quasi-experimental approach (supposedly reflecting the positivist view) and objectivity: 'the initial positivist evaluation was based on the postulate that the object of the evaluation could be observed, described, measured and judged "objectively"' (Nguyen and Otis, 2003: 129). A constructivist alternative was thus adopted that involved community-design of interventions and evaluation based on the needs of and discussions within the population. This approach viewed realities as socially constructed and specific to the individual, and situated evaluation upon human inquiry rather than 'external facts'. This evaluation used strategies to monitor the progress of health professionals and citizens working together (via records of discussions and negotiations in logbooks), producing meeting and analytical reports and conducting brainstorming/group discussions.

The evaluation is to be commended for its grounding within the perspectives of the human actors involved. Beliefs about CHD, though held by individuals, are often socially mediated, widespread and reinforced by experiences of notable others. This phenomenon is illustrated well in lay epidemiology (Davison et al., 1991), in which beliefs about CHD candidacy (some of which conflict with those of empirical epidemiology) are widespread throughout a population and reinforced by experiences of others. These beliefs also influence relevant behaviours, for instance reactions to CHD symptoms (Clark, 2001), perceptions of risk factors (Emslie et al., 2001; Clark, 2003) and self-management (Reid and Clark, 2001). However, wider contexts, social roles, norms and expectations can also impact attendance at programmes by shaping expectations of and reactions to programmes and views of health professionals and expert knowledge systems (Clark et al., 2003). Constructivism, at best, only views these contexts through the perspective of the individual.

Yet, as the authors report, the constructivist intervention also failed because it could not offer any meaningful way to measure programme impact. The sample of citizens who engaged in the process was small and participants were reluctant to act as change agents. The funding body did not provide continued support to a programme that had no agreed specific measures of objective evaluation.

The authors speculate that a lack of resources and oppressive health professionals were detrimental to the implementation process. However, it may also be that an intervention that did not utilize the evidence-base on heart disease prevention had limited public engagement and appeal. While lay beliefs on heart disease and risk do often differ from the more restrictive beliefs and risk-models held by professionals, there is no evidence that the public conceive that an individual's belief of what their risk factor level is actually determines their risk (Clark et al., 2003).

Moreover, the constructivist/hermeneutical approach has problems accounting for the scientific evidence-base supporting the health benefits

of risk factor change and secondary prevention programmes. While this knowledge is not infallible or universal, it would be equally questionable to conclude that nothing is known about how to improve heart health or that knowledge is determined by the perspective of the individual. Similarly, if reality is mind-dependent, so too are the presence and effects of structural forces that affect health outcomes in women, older patients and low-income groups – a stance that is extremely precarious.

To recap: there are both strengths and weaknesses in the positivist and hermeneutical-individualist approaches. The former has appeal in terms of its focus on measuring impacts, its recognition that programme characteristics do matter and its appreciation that programmes have objective outcomes and potential effects on real phenomena. However, in addition to taking inconsistent stances on agency and structure, the positivist approach places excessive emphasis on programmes determining outcomes and does not sufficiently take into account wider determinants of health and contextual factors, and negates individuals' perspectives or mechanisms of change.

The problematic relativism in the constructivist-individualist approach acknowledges the primacy of individuals' perspectives and cognitive states but has difficulty integrating measurable outcomes and overly dismisses existing knowledge and the effects of both programme and contextual factors.

We now propose that critical realism offers a useful and more accurate approach to conceptualizing cardiac rehabilitation. We will then briefly outline a research effort that utilized critical realism to evaluate a cardiac rehabilitation programme.

Critical realism: a brief introduction

Briefly, critical realism is a philosophical approach that was developed in response to the limitations of positivism and relativism (Bhaskar, 1975, 1989). It forms a means to explain and understand 'claims to knowledge, truth, progress and reality through the natural and human sciences' (Connelly, 2001: 115). Critical realism has informed work in a variety of fields, including evaluation (Pawson and Tilley, 1997), economics (Olsen, 1999), organizations (Ackroyd and Fleetwood, 2000), housing (Fitzpatrick, 2005), trade and industry (Morgan and Sayer, 1988), crime prevention (Pawson and Tilley, 1996) and computing (Clegg, 2001). This version of realism also offers a means to change health-related phenomena based on improved understanding and explanation (Wainwright, 1997; Clark, 1998; Proctor, 1998; Williams, 1999, 2003; Connelly, 2001).

Critical realism posits that the various objects, structures and practices that make up reality exist independently of whether their existence, nature or effects are observable, known or understood by humans (Bhaskar, 1975). A distinction is therefore made between experience and research inquiry (which are both fallible and socially specific phenomena) and potentially

hidden, imposing structures and, in the case of disease, physiological universals. Further, reality is seen to extend beyond observable surface phenomena to include mechanisms, structures and powers which can actually or potentially influence what is observed (Bhaskar, 1975). Rather than focusing on predicting observable phenomena, science should focus on causal explanations (Lawson, 2003). To understand how phenomena are generated – in either physical or social realms – science must make recourse to the underlying factors that are or potentially are at play in generating phenomena that may not be irreducible to their constituent factors. As Sayer contends,

> [the] world is characterised by emergence … situations in which the conjunction of two or more features or aspects gives rise to new phenomena, which have properties which are irreducible to those of their constituents, even though the latter are necessary for their existence. (2000: 12)

Thus, though each individual is ultimately comprised of a biological system, cultural practices indeed inform health, outcomes of and reactions to a physiological state.

This is a *generative* ontology whereby associations between phenomena come about as a consequence of hidden mechanisms enacted under certain circumstances. A useful metaphor here is that of a candle, which though causally linked with production of a flame if lit, requires a certain association of circumstances (dry match with the correct chemical composition of tip, dry wick, presence of oxygen, lack of high wind) that must all be present to reach the expected outcome. This view postulates that there are 'real' and dynamic underlying connections between phenomena that may result in causal links under certain conditions at certain times (Pawson and Tilley, 1997). Phenomena are therefore deemed to have emergent properties, that is, characteristics that under the right conditions may result in a certain outcome (Pawson and Tilley, 1997). In the natural sciences, it is conventional in experiments to try to concoct closed systems to control these conditions, and to use control and manipulation to examine and infer the key mechanisms at play. However, in the social world, it is problematic to create artificially such closed systems – objects, causal powers and contextual factors are inherently dynamic.

Critical realism, as these points imply, acknowledges that phenomena exist and operate within open systems and, accordingly, a plethora of different contexts and mechanisms can affect outcomes. These contextual factors may be geographical, historical, social, cultural, environmental and physical (Sayer, 2000). For instance, programmes are enacted in a social context which contains rules, norms, values and associations that either support or inhibit their effectiveness and are also, at least in part, a product of the interpretation of those providing the interventions (Pawson and Tilley, 1997). Furthermore, given the open nature of systems, programmes and interventions cannot be conceptualized as being stable and fixed. Pawson

and Tilley (1997) thus recommend that programmes be enacted under favourable circumstances, in suitable contexts and by capable providers.

This generative conception contrasts with a *successionist* approach to causality evident in the positivist perspective above that aims to identify event regularities derived as the linear and observable sequence of cause and effects that supposedly form causal relationships (Maxwell, 2006). The logic beneath this approach is: apply intervention A to populations B, C and D to cause outcome E.

RCTs and meta-analyses are ascribed a central role in clinical guideline formation and policy decision making (SIGN, 2002). Yet, echoing this positivist approach, they ignore the mechanisms, powers and contexts that actually generate health outcomes. Consequently, when studies are duplicated elsewhere in clinical practice, findings are far less consistent than expected (Riemsma et al., 2003) with little explanation why (Pawson and Tilley, 1997; Maxwell, 2006). At best, the RCT compares: 'two broadly simi-lar aggregates of experimentees and controls mak(ing) it an extremely poor instrument for picking up these harmonious marriages of subject and provision through which programmes really work' (Pawson and Tilley, 1997: 40).

This is not to say that the RCT does not generate useful knowledge. Using the terms of Pawson and Tilley (1997), there will be some winners as well as losers. However, RCTs provide little indication as to how different components of the intervention brought about different effects in specific populations. Nor does it help to identify how unique circumstances in the trial's milieu did affect or may have affected the outcomes. Consequently, there is little understanding of programme results within the population. This creates problems when others elsewhere attempt to introduce the intervention in different settings, with different people and different resources.

A realist approach to secondary prevention programmes

The goal of 'the truth'

A core tenet of critical realism is that claims to truth are resolved and compared through discussion and debate that seeks, on a rational basis, to identify those findings/beliefs that appear to be truthful (Bhaskar, 1998). Thus, critical realism avoids judgemental relativism (all beliefs are of equal truth value), while retaining the view that human knowledge is socially produced.

Explaining outcomes: a focus on causation, mechanisms and contexts

At its centre, a realist approach has the goal of explaining outcomes. This focus on explanation is in part a consequence of its stratified ontology – with outcomes and events being causally linked in a generative manner to underlying powers and tendencies that may only be 'activated' under

particular and varying circumstances. In realist research, this tends to be in the form of comparing the plausibility of competing explanations based on empirical findings and drawing on mid-range theory (Lawson, 1997, 2003). By examining the role of the array of mechanisms (potential and actual, contextual and process) that link programmes and health outcomes, a realist approach warrants that any programme success lies less in its objective characteristics than:

> in the underlying reasons or resources that they offer subjects that generate change … Whether the choices or capacities on offer in an initiative are acted upon depends on the nature of their subjects and the circumstances of the initiative. (Pawson, 2002: 342)

In order to realize and optimize the effectiveness of secondary prevention programmes, researchers must explore 'what works for whom, when and why' (Pawson and Tilley, 1997: 220) taking into account programmes, people and contexts, and both successes and failures. This view encompasses the measurement of impact, but recognizes that the dichotomy of effective versus ineffective provides little insight into improved access and effectiveness. Nor does critical realism place excessive determinism on the capacity of programmes to improve health (thereby ignoring contextual and organizational influences over the effectiveness of programmes) or deny the research evidence that cardiac rehabilitation programmes can improve health.

Confronting and being led by complexity

Realist approaches attempt primarily to account for and examine complexity irrespective of disciplinary orientation or methodological orientation (Sayer, 2000). In contrast to the positivist approach, a realist approach does not control for, abstract or simplify complexity and, in fact, seeks out and embraces complexity. As such, realist approaches to understanding outcomes of programmes should be post-disciplinary, in order to maximize and diversify inquiry. Approaches should also be methodologically eclectic, using qualitative and quantitative approaches as necessary to provide triangulation (Sayer, 2000). One element of this complexity is indeed the experiences and views of agents – but critical realism always suggests that these agents are fallible and their perspectives are open to hegemonic influences and cannot be seen as determining reality.

An open systems view: the multiple health determinants

As critical realism's stratified ontology and critique of the successionist view attest, it is important to examine how elements of the open system interact to influence outcomes. This is not just a matter of comparing different variations of the same intervention (for example, hospital-based versus community-based or individualized versus standardized programmes) but of examining the range of factors, mechanisms and contexts influencing outcomes

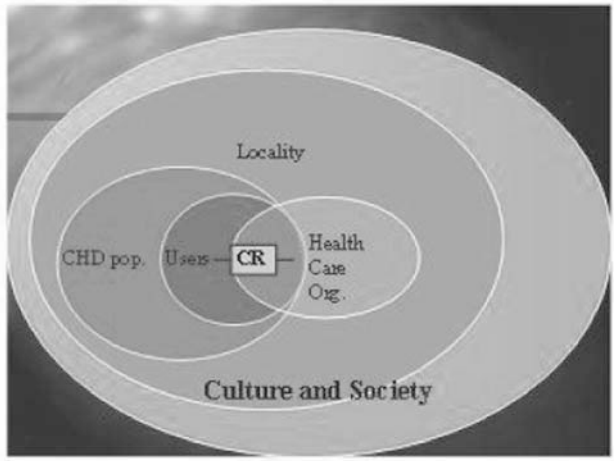

Figure 2 **A realist conception of secondary prevention programmes**

within and across programmes. This follows because: 'programmes are implemented in a changing and permeable social world, and … programme effectiveness may thus be subverted or enhanced through the unanticipated intrusion of new contexts and new causal powers' (Pawson and Tilley, 1997: 218). This approach urges researchers to examine what happens during programmes and afterwards in the community, and to explore how, and by what, outcomes are influenced, in different people across different settings and circumstances (see Figure 2). This approach posits that programmes are embedded within open systems, the processes and outcomes of which are influenced by those involved (users, health professionals and community health and social staff) as well as by the local, social, cultural, organizational and geographical contexts in which these parties interact.

The interplay of factors influencing multiple outcomes

A realist view does not deny the evidence linking cardiovascular disease to biology, lifestyle or social factors, nor the possibility that programmes may positively or negatively affect health outcomes. However, it recognizes that the forces detailed above synergize to influence outcomes. Programmes therefore involve the application of research evidence through organizational, health and social care practices, including different lay populations and professionals. Research outcomes of interest thus extend beyond behavioural change and mortality, towards process-focused factors (Archer and Tritter, 2000). An exploration of patients' decisions to access health services should, for example, extend beyond personal willingness and motivation, to examine the structural factors that enable or constrain attendance (Clark et al., 2003). While proponents of constructivism may reject an outcomes-focused approach (Nguyen and Otis, 2003), critical

realism acknowledges that individual experiences and perspectives (such as embodiment and hermeneutical dimensions) influence behaviour. This does not mean though that health outcomes are not valid or important, or that there are no wider independent probabilistic scientific truths (Sayer, 2000).

An example application of critical realism to research

Critical realism tends to remain either implicit in empirical work (Williams, 2003; Byrne, 2004) or when used more overtly, theoretical and critical in focus (Archer, 1995; Williams, 1999; Allen, 2000; Wainwright and Forbes, 2000). Of course, these initiatives are both appropriate and useful. However, realist-driven empirical work has been notable by its relative absence. Even well-developed approaches (Pawson and Tilley, 1997; Sayer, 2000) are supported by comparatively little published empirical material, have a fairly specific and confined focus and even within these parameters, have had limited empirical refinement. Hence, while realist-approaches offer considerable congruence, usefulness and potential for health-research (Scrambler and Higgs, 2001; McEvoy and Richards, 2003), empirical researchers have to translate various realist tenets into methods. In order to demonstrate the methodological diversity and usefulness of the approach, a programme of research into secondary prevention programmes for heart disease drawing on critical realism is now described. While retaining dimensions of prominent realist-approaches, the programme also draws on the wider literature relating to the application of critical realism to specific methods (Ron, 2002; Olsen and Morgan, 2005). Such programmes may fail to appeal to theoretical purists who advocate strict adherence and expression of all theoretical constructs or, at the other extreme, those without the inclination to consider epistemology or ontology. However, the programme sought to please the former by translating a realist ontology into realist-driven research questions that were also compatible with the substantive questions likely to be of interest to the practical concerns of decision-makers and practitioners (Table 3). Indeed, Scottish Government policy during the mid-stages of the evaluation specified that its findings would guide national strategy (Scottish Executive, 2002b).

Programme context

The Patient Pathway (PP) was introduced as part of the Scottish National Demonstration Project 'Have a Heart Paisley' (HaHP), a regional project addressing the primary and secondary prevention and treatment of CHD. The aim of the project was to improve the health of key populations in the Paisley region of Scotland (population 85,000) and to generate lessons for the prevention of heart disease for Scotland (Scottish Executive, 2002a). The PP (Have a Heart Paisley project group, 2000) aimed to improve the

recovery and rehabilitation of patients diagnosed with different forms of CHD, including early-stage manifestations (such as angina or acute coronary syndrome) and also after myocardial infarction, coronary artery bypass and angioplasty.

The PP, in line with its demonstration project status, sought to implement the latest evidence on the prevention of CHD and thereby offer a wider range of services than current practice (Have a Heart Paisley project group, 2000). Compared to the prior programmes provided locally and the vast majority of other programmes in the UK (Bethell et al., 2001) in 2002 (when it was first implemented), the PP included patients in different stages of CHD referred from general practice and hospitals. Unlike most programmes, the component selection and content were fully individualized based on a comprehensive assessment of each patient's needs and preferences (e.g. smoking cessation) and included one-year follow-up from community nursing staff. As a result, patient diagnoses, disease stages, needs and programme utilization were considerably more diverse and complex than in standard programmes. Programme evaluation was therefore considerably more complicated.

The PP crosses both primary and secondary care sectors and involves a high number and wide diversity of health professionals including rehabilitation specialists (who provided a 12-week hospital programme), over 100 community-based nurses (who provided home visit follow-up support), district nurses, practice nurses and specialist nurses, heath visitors, cardiologists, a clinical psychologist, dieticians, physiotherapists and exercise physiologists.

As part of a larger, population-focused project, evaluation of the PP had to examine its function within the larger HaHP project and, as part of a demonstration project, had to develop meaningful lessons for health improvement elsewhere. An approach to evaluation was therefore needed that extended beyond the positivist model (with its exclusive focus on efficacy and lack of attention to context) towards the development of meaningful lessons for other programme developers and providers in different settings. The PP was seen as one of a range of participants' potential health-influencing factors. Given that changes in cardiovascular risk must occur over the long term (two to five years) for a reduction in mortality (Clark et al., 2005b), it was vital to examine the role the environment and greater community played in influencing health opportunities and outcomes (Macintyre et al., 2002). The proposed research therefore had to reflect the complexities not only of the programme but also of the project, the setting, health behaviour change and of the organizations involved.

Drawing on the theoretical work of realists like Sayer (1992, 2000) and the approach of Pawson and Tilley (1997), the evaluation of the PP conceptualized secondary prevention services using the realist-driven approach described earlier (Clark, 2002). This necessitated making research-based assumptions unfamiliar in current research (see realist rationale: Table 3) and recognizing

Table 3 **Strands of a realist-driven evaluation of a secondary prevention programme**

Research question(s)	*Realist focus*	*Realist rationale*	*Substantive focus*	*Methods*
1) What is the effectiveness of the PP in promoting: • Programme usage? • Behavioural change? • Health/quality of life changes? • Mortality improvements?	Outcomes (Current individualized programme versus past standardized programme)	Programmes have real and objective social, psychological and biological impact whether or not this is recognized by users (Pratschke, 2003) Critical realist ontology is not antagonistic to the measurement of outcomes (Pawson and Tilley 1997; Pratschke, 2003)	Mortality Morbidity Behavioural change: actual & readiness to change Quality of life	Quantitative measurement via hospital data/local disease register (Clark and Findlay, 2005) and telephone survey; comparisons made historically with patients seen in CR in 1999
2) What factors influence programme participation in pts who: 1) Participate? 2) Partially participate? 3) Do not participate?	Mechanisms/contexts and their links to outcomes Perceived mechanisms of affect and context of PP (Clark et al., 2003)	Individual factors such as conceptions and experiences of programmes have an effect on usage and outcomes (Pawson and Tilley, 1997; Sayer, 2000) Use comparisons by outcome to understand mechanisms (Lawson, 2003)	Patient decision making regarding different programme participation outcomes	Qualitative interviews with patients regarding attendance choices (stratified by quantitative measurement in pts who attended vs limited attendance vs low attendance)
3) What factors influence programme participation in pts who are: 1) Women? 2) Low-income patients? 3) Over 65 years old?	Mechanisms/contexts and their links to outcomes Perceived mechanisms of affect and context of PP (Clark et al., 2003)	Conceptions and experiences of programmes of underserved populations have an effect on their usage and outcomes (Pawson and Tilley 1997) Individual and structural factors interplay to influence outcomes (Pawson and Tilley, 1997) Use of comparisons by outcome to understand mechanisms (Lawson, 2003)	Patient decision making regarding programme participation in key underserved patient groups	Qualitative interviews with patients regarding attendance choices (stratified by quantitative measurement in pts who attended vs limited attendance vs low attendance)

4) What factors cause favourable and less favourable outcomes? What are the causal pathways associated with different outcomes?	Underlying mechanisms/ contexts and their links to outcomes (Whelan et al., 2003)	Structural factors influence behaviour (Archer and Tritter, 2000) Regression analyses provide clues to the presence and effects of underlying mechanisms (Ron, 2002)	Identification of structural predictors of individual outcomes	Regression analysis of objective predictors of participation and outcomes Qualitative focus groups of patients into groups stratified by outcome around causal factors promoting and inhibiting willingness and capacity to change behaviour
5) What are the main mechanisms through which participation promotes and inhibits behavioural change?	Underlying mechanisms/ contexts and their links to outcomes (Clark et al. 2005c)	Patients' reactions and the moderating effects of context have a prime influence on outcomes (Pawson and Tilley, 1997)	Mechanisms of affect of programme by context	Mechanisms and context explored with patients with different outcomes stratified by good vs poor outcomes
6) What organizational factors provide a stronger or weaker basis for programme implementation?	Influence of context on outcomes (Clark et al., 2002)	Dimensions of the organizational context in which a programme is delivered will influence events and outcomes (Ackroyd and Fleetwood, 2000)	Organizational culture and programme theory in primary and secondary care settings	Dimensions of rehabilitation, primary and secondary care organizations explored to examine their impact on outcomes
7) What factors associated with implementation of the new programme promoted or inhibited its implementation?	Implementation context (Clark et al. 2005c)	The context in which the programme is delivered and implemented will influence individual outcomes (Ackroyd and Fleetwood, 2000)	Management and implementation culture and programme theory in primary and secondary care settings	Dimensions of wider HaHP and PP programme to examine influence on health professionals and programme implementation

the social and environmental factors that also influence health and health opportunities.

The research programme (Table 3) encompassed some elements of traditional evaluation; for example, an examination of programme effectiveness based on a historical comparison with outcomes in the cohort of patients participating in 1999 (RQ 1: Table 3). This recognized that programmes have objective outcomes and can be more or less effective at facilitating desirable ones albeit as one of a wider set of factors at various levels.

However, to situate the programme within the open system, the evaluation focused on the programme's mechanisms of effect by context. In the general population of eligible patients, examination was undertaken of the interplay of individual, programme-related and contextual factors in terms of programme participation (RQ 2) and effectiveness (RQ 4). The evaluation also examined access in key excluded groups, including women, adults over 65 years and people on low monetary incomes (RQ 3). In this and the general patient population, access was examined in clusters of patients with high, medium and low participation rates with the causative influence of both individual and structural factors on outcomes being explored.

To understand the mechanisms of effect of the programme in different contexts, regression analysis can generate clues about the underlying mechanisms influencing outcomes in different populations (Ron, 2002). Regression analysis identified that key characteristics, including being over 65 years old and female predicted poorer outcomes (Whelan et al., 2003). Qualitative analysis (RQ 5) was used to examine in more detail the mechanisms and contexts causally linked to such patterns (Clark et al., 2004, 2005a). These studies identified that the effectiveness of the programme was determined less by programme content, than by social and corporeal experiences of attending and longer-term health opportunities to exercise safely (Clark et al., 2005a). Individuals who experienced the social and corporeal benefits of rehabilitation but did not continue to exercise were found to have been unable to locate an exercise setting in their area in which they perceived it would be safe for people with heart disease to exercise. Hence, the main contextual factors moderating the social and corporeal benefits of attendance was the availability of community-exercise settings that were seen to be safe.

Finally (RQ 6 and 7), the evaluation examined the influence of the care-providing organizations on outcomes by exploring working cultures, strengths and weaknesses and beliefs throughout the implementation process both in the programme and as part of the wider HaHP project (Clark et al., 2002). These data provided indication that facets such as communication pathways, information management infrastructures and implicit professional perceptions of health determinants impacted on perceived quality of care.

Concluding remarks for practice and research

Secondary prevention programmes seek to promote participation and health in individuals with CHD over the long term. We have argued that the approaches taken to these programmes often view this complex intervention in a simplistic positivist manner or occasionally adopt a constructivist/hermeneutical view that is epistemologically problematic. A critical realist-driven alternative in this area is philosophically strong and encompasses the measurement of outcomes while recognizing the complexity of the multiple factors influencing outcomes. This results in an approach that is attractive to clinicians and funding bodies (who can see conventional indictors of outcomes used), useful to service developers (who can be provided with prescriptive, locally relevant findings and explanations of what works for different populations) and appealing to researchers/theorists (who can develop knowledge beyond that relating to effectiveness that is ontologically based).

Researchers from different health and academic fields have struggled to reconcile the existence and influence of lay epidemiology, clinical knowledge (along with all its associated caveats) and multiple health determinants. Critical realism offers an approach to reconcile these domains that allows theory to strengthen rather than obfuscate inquiry. Critical realist-informed models similar to that described could be readily applied to other areas of health and social care – such as chronic disease management programmes, evidence-based practice and service inequalities – that have outcomes that are a product of multiple underlying mechanisms and contexts. All too often in these areas, individualistic approaches dominate and, despite decades of research, the effectiveness of interventions to promote change in them has been relatively poor.

Critical realism clearly supports a movement from simplistic conceptions of interventions associated with narrow or positivistic approaches. This development is apparent elsewhere. For example, the limitations of RCTs and the need for more mixed-methods approaches to 'complex' evaluation of health programmes are becoming more established (Oakley et al., 2006). While such developments are encouraging, consideration of these approaches should focus not only at the methodological level but also on underlying philosophy. This would ensure that the loaded nature of methodology is acknowledged and the 'logic' of these enquiries is articulated and refined on a reasoned basis.

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Author biography

ALEXANDER CLARK is an Associate Professor at the Faculty of Nursing, University of Alberta. His research is supported by career awards from Alberta Heritage Foundation for Medical Research and the Canadian Institutes of Health Research. His research is focused on understanding and improving health outcomes in people with heart disease, and exploring the complex effects on health of factors associated with people, places and programs. He has undertaken work using qualitative, quatitative and systematics Moreover methods. His work is strongly informed by critical realism and has directly influenced health policy on both sides of the Atlantic.