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The Stent for Life Initiative in Portugal: A Critical Realist Perspective

ABSTRACT

Drawing on the morphogenetic approach proposed by Archer (1995), this study explains how the Stent for Life (SFL) initiative emerged and developed in Portugal and how it was embraced as a means to reduce mortality following acute myocardial infarction. A qualitative research strategy based upon a case study was adopted. Only by conducting qualitative research was it possible to interact context with explanation and produce understandings for the “who”, “when”, “why”, “how” and “what” of SFL in Portugal (Mason, 2018; Ackroyd and Karlsson, 2014; Yin, 2015). Archer’s morphogenetic approach makes analytical dualism explicit and therefore very useful in accounting for the existence of prior material structures and cultural structures that affected (but did not determine) agents’ actions. The investigation revealed that there was morphogenesis (i.e. the former structures were transformed) and that new structures emerged from the intended consequences of agents’ activities.

Keywords – Stent For Life in Portugal; Archer’s morphogenetic approach; Critical realism; ST-segment elevation myocardial infarction.

1. Introduction

The purpose of this paper is to provide an “integrated perspective” (Fincham, 1999) of the Stent for Life (SFL) project in Portugal drawing upon qualitative research (Mason, 2018; Yin, 2015; Miles *et al.*, 2019). SFL initiative was created in 2009 by the European Association of Percutaneous Cardiovascular Interventions (EAPCI), and supported by the Working Group on Acute Cardiac Care of the European Society of Cardiology (ESC), and several national cardiology societies, with the aim of ensuring that ST-segment elevation myocardial infarction (hereinafter, STEMI) patients have equal and timely access to primary percutaneous coronary intervention (PPCI). The SFL initiative is based on medical evidence showing that myocardial revascularisation in patients suffering from acute coronary syndromes reduces both mortality and the rates of non-fatal reinfarction and stroke when compared to pharmacological treatments, including thrombolytic therapy for STEMI. Following the lead of other countries, in February 2011 Portugal joined the SFL project.

A critical realist methodology based upon the morphogenetic approach proposed by Archer (1995) is adopted herein to study why and how has SFL initiate developed in Portugal. Critical realism and the morphogenetic approach are well established in management research, as its growing popularity amongst researchers in the field demonstrates (Price and Martin, 2018; Willmott, 2000; Connelly, 2000, 2004; Mutch, 2002, 2007; Fleetwood, 2004, 2005; Morais, 2011; O’Mahoney and Vincent, 2014; Kempster and Parry, 2006, 2011; Macfarlane *et al.*, 2011; Han, 2010; Kim, 2009, just to mention a few). Archer’s fundamental premise is that any project of change can be fully understood without excess attention being given to either structure and agency. For critical realism (Sayer, 1992, 2000; Bhaskar, 1989, 2008, 2014; Elder-Vass, 2010; Archer, 1995, 2000, 2003, 2007; Bhaskar *et al.*, 2017) structure and agency constitute different levels of social reality that possess distinctive emergent properties, and as a result are not reducible to each other. Drawing on this core idea, we offer an explanatory model for SFL in Portugal inspired by the “dualism” adopted from Archer’s (1995) morphogenetic approach.

The relevance of this research stems from both theoretical and empirical interests. First, it evaluates the extent to which Archer’s morphogenetic approach can be used as a methodological and meta-theoretical basis for understanding and explaining change in healthcare research studies. Secondly, it helps researchers to glean a fuller understanding of the strategies and actions engendered by agents to reduce mortality and morbidity of

patients with acute forms of coronary artery disease in Portugal and to comprehend the extent to which SFL contributes to this end.

The paper is structured as follows. Section 2 discusses the literature that underpins this research. The research methods are then described in Section 3. The paper continues with the presentation of the case study resorting to critical realism and Archer's morphogenetic approach in Section 4. Finally, Section 5 presents the discussion and conclusion.

2. Literature Review

According to critical realism there is a world, comprised of structures that exists independently of actors' knowledge of it (Archer, 1995, 2000, 2003, 2007; Sayer, 1992, 2000; Bhaskar, 1989, 2008, 2014; Elder-Vass, 2010; O'Mahoney and Vincent, 2014; Danermark *et al.*, 2002; Bhaskar *et al.*, 2017). Although the world's existence does not depend on actors' awareness, actors are able to intervene (i.e. to exert agency) and change the world (Archer, 1995, 2000, 2003, 2007). Structure and agency constitute two different levels of stratified social reality, which despite in permanent interaction are irreducible to each other (Archer, 1995, 2000, 2003, 2007; Elder-Vass, 2010; Kempster and Parry, 2014; Bhaskar *et al.*, 2017). Structures can be described as "a system of relationships between objects, positions and collectivities that explain their tendencies to act in a particular way" (Ashraf and Uddin, 2013, p. 189). Each structure holds causal powers that give agents occupying positions within the structure capacities to behave in certain ways (cf. Sayer, 2000; Elder-Vass, 2010; Bhaskar, 1989, 2008; Bhaskar *et al.*, 2017). According to critical realists, structures and their causal powers are in the domain of real whereas the experienced events are located in the domain of empirical, that is the level of actors' sensations, impressions and perceptions of reality (Sayer, 2000; O'Mahoney and Vincent, 2014). Scholars argue that despite the power of structures, they do not determine the form of events (Archer, 1995, 2000, 2003, 2007). Likewise, human agency understood as "the power of individuals to interpret and reflect on these structural pressures and take actions that they deem appropriate, even against the structural pressures" (Ashraf and Uddin, 2013, p. 190) needs to be considered when seeking to explain social phenomena. Therefore, for critical realists, events are triggered in the domain of actual every time structures' causal powers are activated, and this intermediates the domain of real and the domain of empirical (Ackroyd and Karlsson, 2014; Bhaskar, 2008; Bhaskar *et al.*, 2017). As soon as events are identified and experienced by actors, they are transferred into the domain of empirical. These three levels are autonomous in permanent interaction and

embody the relationship between structure and agency. Structures and agency are thus equally important and should not be neglected at each other's expense; if actions by agents need to be considered in the context of the wider structural conditions that involve agents' activities, structures can only exert influence once agents occupy positions within structures and activate their causal powers (Archer, 1995; Sayer, 2000; Elder-Vass, 2010; Bhaskar, 2008; Bhaskar *et al.*, 2017).

This poses a central dilemma to critical realism, which can be described as how structure and agency can be linked without either conflating agency to structure (upward conflation) or structure to agency (downward conflation), or holding the two as mutually constitutive and precluding any examination of their interplay (central conflation) (Archer, 1995). Conflationary social theory advances explanation, which reduces structure to agency and vice versa, depriving structure and agency of their independent properties and powers. Moreover, the view offered by Giddens's structuration theory (Giddens, 1984; Giddens and Pierson, 1998), that structure is simultaneously the medium and outcome of action and that agents cannot act without drawing upon structures whose own existence depends upon instantiation by agents, shares the problematic nature of all forms of conflationary theory (Archer, 1995).

The morphogenetic approach is an explanatory methodology that is based on analytical dualism (i.e. that structure and agency are analytically separable)¹. It was developed as the practical complement of critical realism and with the aim of supplying a "genuine method of conceptualising how the interplay between structure and agency can actually be analysed over time and space" (Archer, 1995, p. 15); the approach seeks to help researchers to understand how structure and agency can be linked "rather than be sinking one into the other" (*ibid*, p. 65). Accordingly, social outcomes can only be understood through the analysis of the processes by which structure and agency shape and reshape one another over time. Without the inclusion of temporality in social analysis and the study of the interplay of structure and agency over time, the problem of structure and agency, (which has become a central dilemma in social theory today) can never be resolved. Summing up, the morphogenetic approach highlights that explaining a social phenomenon involves analysing not only structures at work but also agency and how they interact temporally (Archer, 1995, 2000, 2003, 2007; Price and Martin, 2018).

Two basic propositions can be put forward to summarise this approach (Archer, 1995, p. 76): (i) that structure necessarily pre-dates the action(s) that lead(s) to its reproduction or

transformation; and (ii) that structural elaboration necessarily post-dates those actions. Figure 1 represents the morphogenetic sequence proposed by Archer.

[Insert Figure 1 about here]

The morphogenetic sequence can be described by the projection of three lines backward and forward: T1 represents the structural conditioning; T2-T3 relates to social interaction and to the moment of agency; and T4 to the structural elaboration, that is, the outcomes that result from agency. There is “morphogenesis” when processes tend to elaborate or change a system’s given form, structure or state; in opposition, if processes in a complex system tend to maintain the above unchanged there is “morphostasis”. These three lines represent a morphogenetic cycle and would connect up with the anterior and posterior morphogenetic cycles. A new morphogenetic cycle is restarted with structural elaboration as it introduces a new set of conditional influences upon interaction (Archer, 1995).

Descriptions are given below of each of the three lines that are part of the morphogenetic sequence presented in Figure 1.

Structural conditioning – T1

The first task for a researcher is to identify the structural conditions at time T1. To this end, the concept of “laminated system” (Baskar, 1993; Elder-Vass, 2010; Price and Martin, 2017) is paramount because identifying structures entails understanding how different entities relate to each other as part of a greater whole (O’Mahoney and Vincent, 2014, p. 7). At this stage researchers look for the two types of structures: material and ideal (or cultural). Material structures are the internal relationships between objects that are mainly human or material. Ideal structures refer to the “world of ideas” (Archer, 1995, p. 179). All theories, beliefs, and writings, which make certain truth claims and thus stand in some logical relationship with each other (i.e. that are in a propositional form) constitute the ideal (cultural) structures.

Social interaction – T2 to T3

After identifying the material and ideal (cultural) structures at time T1, researchers need to focus on agents, their power and how they act upon structures. Structures provide agents with vested interests and the situational logic of action (Archer, 1995; Bhaskar, 1989, 2008; Bhaskar *et al.*, 2017). Agents occupying structural positions are affected by

the powers and interests of positions, which urge them to embark on change or to keep structures unaltered. Thus, agents might look for strategies that change the structure they inherit or that maintain it according to the nature of the position and relationships they hold (*ibid*). When actions engendered by agents result in a change in the structural context, , morphogenesis occurs at time T4. On the other hand, if the structural context continues there is morphostasis (Archer, 1995).

Agents are not equal: they can be either corporate or primary. Corporate agents are those that are articulated and organised. In opposition, primary agents are unarticulated and unorganised. Whilst the former maintain/re-model the socio-cultural system and its institutional parts, the latter work within it and its parts. As Archer observes “corporate agents alter the context in which primary agents live and primary agents alter the environment in which corporate agents operate” (Archer, 1995, p. 265).

Structural elaboration – T4

The connective mechanism between phase T2-T3 and phase T4 works through exchange transactions and power relations (*ibid*, p. 296). In other words, structural elaboration occurs through exchange and power. There are three kinds of resource according to Archer: wealth, expertise, and political sanctions. The agents that have the greatest access to these resources will be in the best bargaining position, and as such best positioned to introduce changes in structures.

3. Research Methods

This study employs qualitative research to understand why and how the Stent for Life project emerged and developed in Portugal and how it was embraced as a means to reduce mortality following acute myocardial infarction. Only by conducting qualitative research were we able to interact context with explanation and produce understandings for the “who”, “when”, “why”, “how” and “what” of SFL in Portugal (Mason, 2018; Ackroyd and Karlsson, 2014; Yin, 2015). To understand the processes and mechanisms that are at work in SFL in Portugal, a case study was conducted between January 2014 and May 2015 (Yin, 2014, 2018; Swanborn, 2010; Kessler and Bach, 2014; Vincent and Wapshott, 2014; see also, Ackroyd and Karlsson, 2014 for the research techniques to use when drawing on critical realism). Case studies have been described as the preferred research method when a “how” or “why” question is being asked, the researcher has little or no control over events, and the focus is on a contemporary set of events within a real life

context (see Yin, 2014, p. 14). This investigation meets these conditions. Furthermore, case based research, which has been highlighted as the basic design for realist studies, was adopted because of its ability “to bring to light formative processes which cause particular outcomes” (Ackroyd and Karlsson, 2014, p. 24; see also, Vincent and Wapshott, 2014).

As the focus of the research was on the specific case, and prevailing theory (in our case critical realism and Archer’s morphogenetic approach) was used to understand and explain the specific rather than to produce generalisations, an explanatory case study was adopted (Ryan *et al.*, 2002; Yin, 2018). In the research process, abduction was the main logic of discovery employed given researchers’ aim of combining different sources of evidence with theory to produce explanations of the mechanisms behind SFL in Portugal (Ackroyd and Karlsson, 2014; O’Mahoney and Vincent, 2014; Bhaskar, 2014; Bhaskar *et al.*, 2017). Following Yin’s (2014, 2018) recommendations, five main steps were followed to conduct the research: (i) designing the case study; (ii) preparing to collect evidence; (iii) collecting case study evidence; (iv) analysing evidence; and (v) reporting the case study. These steps were carried out interactively rather than in a simple linear way (Ryan *et al.*, 2002; Yin, 2018). Furthermore, researchers used Yin’s (2014, 2018) four tests (construct validity, internal and external validity, and reliability) to evaluate the quality of the research design. Prior to the start of the study, access to the field was negotiated with the SFL Portugal champion. At the same time, researchers looked on the Internet for general information on SFL and the evolution of myocardial infarction disease in Portugal (Ferreira *et al.*, 2013) and OECD countries (OECD, 2013). Multiple sources of evidence were adopted in order to enable triangulation of data (Smith and Elger, 2014) and to ensure that researchers were not reducing social phenomena to their discursive descriptions, or to their component parts (O’Mahoney and Vincent, 2014; Ackroyd and Karlsson, 2014; Sims-Schouten and Riley, 2014; see also, Ackroyd, 2004, 2009; Bhaskar *et al.*, 2017). These sources included written documentation, namely a guide to SFL (titled “Stent for Life: How to Guide”), power point slides on the SFL initiative presented by the SFL champion and the SFL national project coordinator at the Portuguese Association of Cardiovascular Intervention (APIC) conferences, documents prepared for the SFL project manager for Europe and the SFL European Executive Board (titled “Portugal Stent for Life Initiative Action Checklist”, “Stent for Life Initiative Country Situation”, “Stent for Life Initiative Barriers”, “Stent for Life Initiative Reporting Template” – all for the years of 2011, 2012, 2013, and 2014), minutes from

SFL task force meetings, SFL newsletters, e-mails exchanged between the SFL national project coordinator and the SFL task force, visits to the websites of the European Society of Cardiology (ESC), the European Association of Percutaneous Cardiovascular Interventions (EAPCI), ESC Working Group on Acute Cardiac Care, the Portuguese Society of Cardiology, and the Portuguese Association of Cardiovascular Intervention, and in-depth semi-structured interviews. In total, eight in-depth interviews (each lasting 80 to 120 minutes) were conducted with key actors of the SFL Portugal project during 2014 and 2015. Table 1 summarises these interviews.

[Insert Table 1 about here]

Interviews were tape-recorded and later transcribed. A guide was prepared prior to each of the interviews (Hammersley and Atkinson, 2007; Smith and Elger, 2014). A case study database was developed to ease access to the data gathered. Data were analysed through three concurrent and interwoven flows of activity (Miles and Huberman, 1994; Miles *et al.*, 2019): data reduction, data display, and conclusion drawing/verification. When reducing data, researchers looked for repetition, regularities, and patterns in order to subsume the main themes covered by evidence and find clusters in the information (Hycner, 1985). A chain of evidence was built to strengthen this activity. Displays (in the form of matrixes) were used to organise information and to help find explanations and possible configurations (Corbin and Strauss, 2008). At this point of the analysis, Archer's morphogenetic approach was found to be very valuable as it provided researchers with a framework that helped to make sense of evidence. As the analysis proceeded, conclusions were drawn. Finally, during the writing of the case study report, key informants (SFL Portugal champion and SFL national project coordinator) were asked to review the researchers' draft report.

4. The Empirical Study

Drawing on Archer's morphogenetic approach, we analyse the Stent for Life Initiative (SFL) in Portugal in three different analytical phases: T1 (period 2008-2010), which corresponds to the structures that enmeshed the development of the project; T2 to T3 (years 2011-2013), which relates to the actions initiated by agents to increase the access rate to primary percutaneous coronary intervention (PPCI); and T4 (year 2014), which is associated with the outcomes of the SFL in Portugal.

First analytical phase - T1(Period 2008-2010)

In T1 we examine the material and ideal/cultural structures. These structures had themselves resulted from the social interaction in the previous morphogenetic cycle. These were the conditions that led to the development of SFL in Portugal, and which we need to bring forward to understand the context for agency at time T2-T3.

In order to identify the material and ideal (cultural) structures at work, we followed Sayer's (1992) recommendation to pose certain questions: What does the existence of objects (in our case, SFL in Portugal) presuppose?; What must be present in order to assure its existence? Answering these questions permitted us to identify the transfactual conditions that had to be present for SFL project to develop in Portugal.

A literature review, Internet search, interviews, and documents published elsewhere (OECD, 2013; Ferreira *et al.*, 2013) were used to enter into the domain of real. As mentioned above, researchers must penetrate the surface of reality to access the domain of real in which the structures inhabit, in order to explain critical realism. In doing so, researchers sought to obtain a "thick description" of the structures at work and to set the scene to identify the general patterns of activities associated with the mechanisms to explore (Vincent and Wapshott, 2014). Evidence gathered shows us that over the last two decades, coronary heart disease has been recognised as one of the main causes of mortality in Europe, accounting for 1.92 million deaths each year (Laut *et al.*, 2011; Tajani, 2012), meaning that one in five persons dies from the disease (*ibid*). Moreover, it is well acknowledged that reperfusion therapy is the most beneficial part of the treatment when patients are suffering from an acute myocardial infarction (Knot *et al.*, 2009). Thrombolytic treatment (in the pre-hospital or in-hospital setting), PPCI, or, a combination of both, are the different modes of reperfusion therapy. However, following the publication in the early 2000s of two large clinical trials reporting that PPCI offered a lower number of reinfarctions and hence better clinical results than other forms of treatments (Andersen *et al.*, 2003; Widimsky *et al.*, 2000), PPCI became the preferred treatment for patients with acute ST-segment elevation myocardial infarction. Additional scientific studies have since confirmed the medical advantages of PPCI over fibrinolytic therapy (Widimsky *et al.* 2010; Kristensen *et al.*, 2012). This explains why the European Society of Cardiology (ESC) recommends PPCI as the most appropriate treatment for patients with STEMI (Steg *et al.*, 2012). Accordingly, this reperfusion strategy should be adopted when three conditions apply: (i) first medical contact-to-balloon time or door-to-

balloon time² is less than 90-120 minutes; (ii) the team is experienced, performing more than 75 percutaneous coronary intervention cases per year; and (iii) the patient is treated in a high-volume centre that treats more than 36 PPCI cases per year (Laut *et al.*, 2011, p. 108). PPCI remains superior to thrombolysis treatment even when transfer to an angioplasty centre is required (Knot *et al.*, 2009, p. 301).

The European Society of Cardiology established clear guidelines for treating STEMI patients. Despite this, a first large-scale study conducted in 30 different European countries in 2007/2008 (Widimsky *et al.*, 2010; see also Laut *et al.*, 2013) found that only 40% to 45% of STEMI patients were treated with PPCI and that thrombolysis remained the most frequently used reperfusion therapy, especially in Southern European and Balkan countries (see also, Laut *et al.*, 2011). Furthermore, this investigation revealed that many patients in these countries were not receiving reperfusion treatment at all; the situation was substantially better in North, West, and Central Europe, where PPCI was found to be used in a large proportion of myocardial infarction patients.

Overall concern for improving treatments of acute myocardial infarctions in Southern European and Balkan countries drove EAPCI, EuroPCR³, and the ESC Working Group on Acute Cardiac Care with the support of EUCOMED to organise SFL in 2009 (Knot *et al.*, 2009). The main goal was to ensure that the majority of STEMI patients would have equal access to the life-saving potential of percutaneous coronary intervention. Countries in which PPCI was used in a minority of acute myocardial infarction patients were set as the target for SFL. The project was rolled out in Bulgaria, France, Greece, Serbia, Spain, and Turkey after National Cardiology Societies declared their commitment at the ESC 2009 congress in Barcelona, and in following years other countries joined the initiative⁴. SFL targets were: (i) to increase the use of PPCI to more than 70% of all STEMI patients; (ii) to achieve PPCI rates of more than 600 per million inhabitants per year; and (iii) to offer a 24-hour 7 days a week (24/7) PPCI service at all invasive facilities in order to cover the countries' STEMI population needs (*ibid*).

In Portugal, coronary heart disease is the second cause of death (Ferreira *et al.*, 2013). Widimsky *et al.*'s (2012) study reported that in 2007/2008 more than 50% of Portuguese patients suffering with ST-segment elevation myocardial infarction had no access to any form of reperfusion therapy and that only 19% of these patients benefited from PPCI (see also Pereira *et al.*, 2014). A hypothetical explanation for this was that STEMI patients arrived at hospitals more than 12 hours after the onset of symptoms (Santos *et al.*, 2009). Thrombolytic treatment was still the most popular type of treatment offered by hospitals

in the country at that time. Moreover, the time between the onset of pain and the moment of first medical contact (i.e., patient delay)⁵ was reported as being too long (Pereira *et al.*, 2014).

Based on documentary evidence and interviews, we were able to understand the material and ideal (cultural) structures that led to the development of the Stent for Life project in Portugal (Archer, 1995). The material structures comprised internally related positions between the European Society of Cardiology, EAPCI, EuroPCR, the ESC Working Group on Acute Cardiac Care, EUCOMED, the Portuguese Society of Cardiology, and the Portuguese Association of Cardiovascular Intervention (APIC). The relationship dynamics between all these entities, grounded on common concerns about high levels of mortality and morbidity in patients suffering from STEMI in ESC member countries, determined the development of the SFL project in Portugal. The relationship between these entities can be described as one of internal necessity and complementarity, as the existence of one organisation is linked to the existence of the others and to the objective of developing forms of treating and reducing cardiovascular disease.

According to Archer (1995), organisations follow a strategy of protection in these circumstances; that is, they tend to follow similar courses of action supporting the actions of each other. Thus, as soon as the Portuguese Society of Cardiology and the Portuguese Association of Cardiovascular Intervention (APIC) expressed its willingness to join the Stent for Life project, it was endorsed by the other organisations.

Apart from these material structures, we need to consider the relationship between Portuguese public hospitals and the National Institute of Medical Emergency (hereinafter, INEM). INEM was created in 1981 to provide help to victims of accidents or sudden illness in Portugal, by sending the appropriate means of assistance, including ambulances to transport patients to appropriate health facilities. INEM and Portuguese public hospitals are contingently linked since each entity can exist without the other despite the complementarity of the internal relationships established between them. Archer (1995) suggests that when the nature of the relations is one of contingency and there is complementarity, there are structural pressures pushing agents to follow a strategy of opportunism.

Before the development of SFL project in Portugal, INEM was criticised for often transporting STEMI patients to hospitals that were not prepared to deliver primary percutaneous coronary intervention, and for failing to coordinate with cardiologists and coronary disease hospitals. A final material structure that affected agents relates to the

internal relations between the hospitals' emergency services and cardio-services. Interviewees referred to a lack of coordination between the emergency services and the cardio-services of hospitals, observing that the Manchester screening system⁶ often assessed the symptoms of STEMI patients as not urgent. Accordingly, medical symptoms of myocardial infarction were frequently confounded with signs of other illnesses or less severe physical conditions, which delayed patients' timely access to primary percutaneous coronary intervention.

Second analytical phase – T2 to T3 (Period 2011-2013)

Understanding the material structures at time T1 is crucial to explaining why SFL was initiated. Nonetheless, identifying the ideal (cultural) structures at work during the same period is equally important if we wish to understand the structural pressures on agents to embark on change. The central organising idea was that PPCI was used in a minority of acute myocardial infarction patients in Southern Europe. Portugal was not only reported as one of the European countries in which PPCI was least used in all STEMI patients but also where a large number of patients were not receiving any reperfusion treatment at all (Widimsky *et al.*, 2010). Thus, despite the European Society of Cardiology's efforts to promote PPCI as the preferred treatment for STEMI patients, treatments scientifically regarded as less appropriate (e.g. fibrinolytic therapy) were still in use, or even worse, no treatments were administered to patients. Moreover, the Portuguese population as a whole lacked knowledge about the typical symptoms of coronary heart disease. Also, there was little awareness of the fact that it is vital to call "112" (the emergency call number) when suffering from these symptoms. As a result of this often STEMI patients were taken to other hospitals before being transferred to a hospital offering primary angioplasty services (24 hour / 7 day cath lab). All these features together resulted in a high level of STEMI mortality in the country (Santos *et al.*, 2009; Widimsky *et al.*, 2010).

These were the structures at play before the development of SFL in Portugal. In order to understand the social interaction at time T2-T3, we focus now on the actions and strategies followed by agents. These actions and strategies arose out of the (material and ideal) structures at time T1. Interviews with key agents proved crucial at this stage (Smith and Elger, 2014). The social interaction phase in this study started when a well-known Portuguese cardiologist (Dr. Hélder Pereira) attended the ESC 2009 congress in Barcelona and became interested in the SFL project. As he explains:

This [the high level of mortality and morbidity of patients suffering from acute coronary syndromes] was something that concerned me. When I came across the Stent for Life initiative I thought it was a good opportunity to improve things in Portugal.

At the time, Dr. Pereira did not hold any management role in either the hospital where he worked or the European or Portuguese Society of Cardiology. Nevertheless, this did not prevent him from establishing contacts with the European Association of Percutaneous Cardiovascular Interventions (EAPCI) members who joined the SFL. At this stage, Dr. Pereira was a primary agent as he was acting as an individual. This might explain why it was only in 2010 (after the Portuguese Association of Cardiovascular Intervention (APIC)⁷ was formed and Dr. Pereira became its general secretary) that he was able to present a formal proposal for Portugal to enter the SFL initiative. According to Dr. Pereira:

The first time I contacted the president of EAPCI was in 2009. I expressed my interest in introducing the SFL project in Portugal at that time... Yet it seems that the right conditions for developing the project were not met in 2009 ...It was only two years later that Portugal was able to join the project.

The support of the presidents of both APIC and the Portuguese Society of Cardiology was very important at this stage. Their endorsement of the project was a consequence of Pereira's new role as a corporate agent. In February 2011, Portugal became the 10th country to join the initiative. It was not difficult to convince the SFL project manager for Europe and the SFL European Executive Board that Portugal should join the SFL as Southern European countries had already been identified as ones where medical fibrinolysis continued to be the prevailing treatment and many STEMI patients were not receiving reperfusion treatment (cf. Widimsky *et al.*, 2010). Portugal was thus regarded as one of the countries in which the SFL project could contribute significantly to saving lives by improving access to PPCI.

In order to achieve the SFL project objectives, Dr. Pereira had to build a local structure comprising a steering committee, a task force, and a national project coordinator, which he headed as the country champion of SFL. The members of the steering committee were strategically chosen from among key actors in the Portuguese healthcare sector with the aim of providing broad strategic oversight for the SFL initiative and overseeing the gathering of scientific evidence. They were: APIC president; former APIC president;

coordinator of Cardiovascular Diseases at the Ministry of Health; and the president of the National Institute of Medical Emergency (INEM). Furthermore, the steering committee would assist Dr. Pereira in leading the SFL task force and developing the country implementation plan. The role of the SFL Portugal task force was also well defined; among other things its responsibilities included identifying barriers to the effective use of PPCI, securing additional local industry as partners if necessary, and developing tactical details for the country's implementation plan. Strategically, it comprised key SFL stakeholders that could dedicate resources and expertise to the project; its members included interventional cardiologists, industry partners (such as Abbott Vascular, Medtronic, Astrazeneca, Johnson & Johnson, Lilly, Tinkle, Galp Energia and Zon) and academics. Finally, Dr. Pereira chose a former manager from the pharmaceutical industry to be the national project coordinator who would help him ensure the strategy was implemented and that the objectives set for SFL could be met. The national project coordinator also had to carry out other activities, namely: (i) liaise with and report to the SFL steering committee; (ii) coordinate the SFL partners and the resources at their disposal; (iii) provide administrative support to the SFL country champion; and (iv) liaise with the SFL project manager Europe and with other SFL national project coordinators. After building the local structure, Dr. Pereira was asked to map and analyse the PPCI situation as regards the network and coverage in Portugal. Table 2 summarises the country situation he found in May 2011.

[Insert Table 2 about here]

Gathering this information helped Dr. Pereira to gain a good understanding of the local PPCI situation. The mapped of Portugal's PPCI situation allowed the specific barriers to effective reperfusion in the country to be identified. Working together with both the SFL steering committee and the task force, Dr. Pereira made a comprehensive analysis of patients' behaviour. He observed:

[When we started the SFL project] we concluded that there was little awareness of STEMI symptoms among patients and that only 23% of STEMI patients were calling 112 [the emergency call number].

These two aspects (that is, patients' difficulty in recognising STEMI symptoms and their lack of awareness that they should call 112 to hasten their access to PPCI) were identified

by Dr. Pereira and his team as “patient related barriers”. Additionally, scrutiny of the emergency medical system network and hospitals revealed two other types of barrier (i) barriers related to emergency medical services; and (ii) hospital-related barriers. When referring to barriers related to the emergency medical services, the SFL national project coordinator pointed out:

When we started the SFL project in 2011, we analysed the communication process from the emergency call to the hospital; at that time, there was no direct contact between INEM and the cath labs...we were very concerned because there was an enormous amount of time between the call and the patient being assisted by an interventional cardiologist...

She continued:

There was also a second problem... Because many STEMI patients were going to non-PPCI hospitals, they had to be transported to a PPCI hospital by an INEM ambulance ... however, patients can only be transported between hospitals with a doctor present... unfortunately, often doctors are not available to accompany patients and transportation has to be delayed.

The lengthy communication process from the emergency call to the hospital and the need to ensure inter-hospital transportation with a doctor were therefore advanced by Dr. Pereira and SFL staff as two important obstacles in emergency medical services. In relation to hospital-related barriers, Dr. Pereira found two other issues. The first concerned the high percentage of STEMI patients that were classified as non-urgent under the Manchester screening system when they arrived at a hospital by their own means. The second issue related to a cath lab in the Alentejo region⁸ that was only in operation two days per week.

The barriers to effective reperfusion ascertained at the start of the SFL initiative in Portugal (“moment zero”) were presented publicly (2nd meeting of APIC, 22-23 October, 2011) in order to attract public support for the project. Once the barriers were identified, Dr. Pereira (together with the steering committee) moved to the definition of objectives for SFL in Portugal and to the development of a strategic plan for the next three years. Three objectives were set for the period 2011-2014: (i) to increase the use of PPCI to more than 70% of all STEMI patients; (ii) to achieve a PPCI rate of at least 400 per million inhabitants within two years; and (iii) to offer a 24-hour service 7 days a week (24/7) in

all the cath labs in the country. A strategic plan was defined to meet these objectives. The plan comprised the launch of a public campaign called “Act now. Save a life”, to increase awareness about acute coronary syndromes and the need to act quickly and call 112. With the help of SFL partners, Dr. Pereira was able to advertise the campaign extensively in Portuguese newspapers, radio, and TV⁹. Concurrently, awareness raising activities were undertaken with the population. These included the distribution of leaflets, pins, and posters, and cardiovascular disease screening in various locations throughout the country. The strategic plan also encompassed working to improve communication between emergency medical services (INEM ambulances) and PPCI centres and the need to find solutions for rapid secondary transport of patients from non-PPCI hospitals to PPCI centres. Furthermore, the plan established that intra-hospital coordination and communication (i.e., between emergency services and the cardio-services of a hospital) should be improved. The strategic plan was presented publicly and barriers were also discussed at this meeting (2nd meeting of APIC). Dr. Pereira was aware that SFL should be open and transparent about its objectives and activities, and that all partners and stakeholders should have easy access to plans and results. He also understood the importance of demonstrating the project’s success to SFL stakeholders. To this end, the progress of initiatives was monitored and communicated on a periodic basis to partners, funders of the project, and other stakeholders.

One of the ways success was measured was through a national survey in the 24/7 cath labs to record all catheterised patients exhibiting STEMI symptoms over a period of one month (normally between May and June each year). The surveys were carried out at specific time-points: the first immediately after Portugal joined the SFL project (“moment zero”) and the remaining in 2012 (“moment one”), 2013 (“moment two”) and 2014 (“moment three”). At each moment, the type of “first medical contact” (FMC) was registered, as well as the means of transport used by patients to get to the hospital. A record was made of whenever the patients attended another hospital or healthcare facility before reaching a hospital with PPCI. Moreover, the length of time between the onset of pain and the primary angioplasty treatments was compared for moment zero and the remaining moments to determine whether the time between FMC and the first electrocardiogram was not more than 10 minutes and the elapsed time from FMC and PPCI was not more than 90 minutes.

Third analytical phase – T4 (year 2014)

As a result of the social interaction phase we have just described, changes in the earlier structures ensued (structural elaboration in Archer's morphogenetic sequence). Table 3 presents the country situation in June 2014, three years after SFL's introduction in Portugal.

[Insert Table 3 about here]

These changes were diverse and brought an overall improvement in terms of the (material and cultural) structural conditions related to the treatment of ST-segment elevation myocardial infarction in Portugal. For instance, between moment zero (June 2011) and moment three (June 2014), there was a substantial growth in the number of STEMI patients that used the national number for medical emergencies (112) when in need of assistance. The percentage of patients calling the emergency number rose from just 23% in 2011 to 35% in 2014 (cf. Tables 2 and 3). This seems to indicate that there was an increase in the Portuguese population's awareness of the symptoms associated with myocardial infarction and a better understanding of the importance of acting quickly by calling 112. Simultaneously, there was a decrease in the number of STEMI patients that went first to hospitals that were not prepared for delivering primary angioplasty (24 hour/7 day) services. This might be explained by the fact that INEM began to telephone cardiologists directly at hospitals providing PPCI during this period; furthermore, additional INEM ambulances were equipped with telemetry and facilities to transfer electrocardiograms to hospitals (87 ambulances in 2014 vs. 77 in 2011). In addition to this, INEM started to assure inter-hospital secondary transport between non-PPCI hospitals and hospitals providing these treatments.

Due to these efforts, the rate of no reperfusion therapy dropped from 37.3% in 2011 to 7% in 2014 and the usage rate of PPCI increased from 63% in 2011 to 68% in 2014 (see Tables 2 and 3). Similarly, the percentage of use of PPCI in STEMI patients rose from 19% in 2011 to 68% in 2014. In 2014, PPCI treatments per million inhabitants stood at 337, up from 280 in 2011. Summing up, significant improvements had been made in hospital networks; together with advances in coordination in pre-hospital and inter-hospital transportation, this minimised treatment delays. A positive impact was thus observed following the implementation of the SFL project in Portugal. The SFL public awareness campaign on myocardial infarction symptoms ("Act now. Save a Life") engendered by Dr. Pereira and SFL task force proved to be a determining factor in the project.

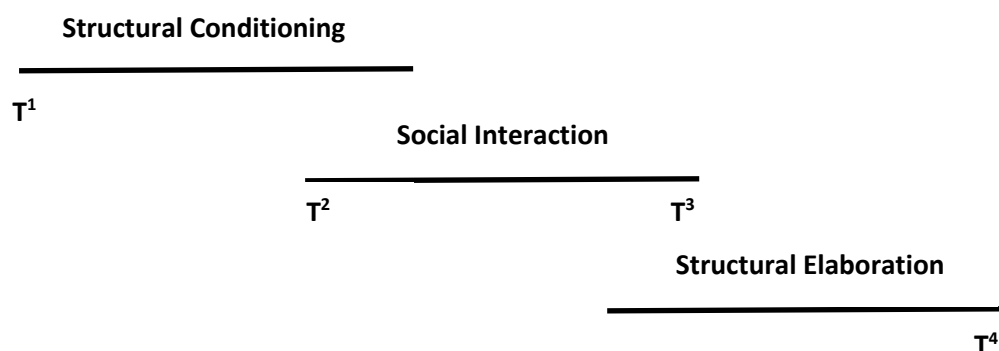
5. Discussion and Conclusions

This paper adopted Archer's morphogenetic approach (1995) as a supplement to critical realism to explain how the SFL initiative emerged and developed in Portugal and how this initiative helped to reduce mortality and morbidity caused by acute ST-segment elevation myocardial infarction. By making analytical dualism explicit (i.e., that structure and agency are two different yet related levels of stratified social reality that interact over time), Archer's morphogenetic approach was found to be very useful in accounting for the "who", "when", "why", "how", and "what" of the SFL in Portugal. The empirics of the study hinted at the existence of prior material structures (lack of communication between the emergency medical services ambulances and PPCI centres, high patient delay, poor performance of transportation between hospitals, ineffective communication processes between hospital emergency and cardio-surgery units), and cultural structures (lack of awareness of myocardial infarction symptoms and the need to call the emergency services number quickly) that affected (but did not determine) our agent's (Dr. Pereira) actions. To achieve his purposes of boosting the use of PPCI to more than 70% of all STEMI patients, achieving a PPCI rate of at least 400 per million inhabitants, and offering a 24-hour service 7 days a week (24/7), our agent had to reflect on the pre-existing structural conditions and devise strategies (e.g., becoming APIC's general secretary, joining SFL, and attracting allies for the SFL project in Portugal) that could help him achieve the desired changes. Gathering documents about SFL and myocardial infarction in Portugal along with interviews with key actors in the SFL initiative were very important to understand the interactions and for the elaboration of new structures (Ackroyd and Karlsson, 2014). In this respect, our investigation revealed that there was morphogenesis (i.e. the earlier structures were transformed) and that new structures emerged from the intentional consequences of Dr. Pereira's activities. We thus argue that the structural elaboration post-dated the sequence of actions that gave rise to it. These new structures comprised a greater awareness of the 112 emergency call service and of the symptoms of infarction, an improvement in communication between INEM ambulances and hospitals providing PPCI treatments, rapid secondary transport of patients from non-PPCI hospitals to PPCI centres, and an improvement in intra-hospital coordination.

The contributions of this research are twofold. First, the study demonstrates how Archer's morphogenetic approach can be successfully adopted as a methodological and meta-

theoretical basis to further understanding of the processes by which structure and agency shape and re-shape one another over time (Archer, 1995, 2003). The case of the Stent for Life initiative in Portugal illustrates that material and cultural structures are not only irreducible to people as structures pre-exist agency. By this we mean that Dr. Pereira's actions and initiatives did not occur in a vacuum, but rather took place in a structural context, which pre-existed any attempt at activity. However, Dr. Pereira was not a puppet of prevailing material and cultural structures, as he had his own emergent properties associated with his role as agent that gave him the opportunity to transform structures (cf. O'Mahoney and Vincent, 2014; Bhaskar, 1989, 2008; Ackroyd and Karlsson, 2014; Bhaskar *et al.*, 2017). We argue that by making analytical dualism explicit, the morphogenetic approach not only enables us to identify structures that affected (but did not determine) Dr. Pereira's actions, but also to analyse how our agent was able to exert agency and engender structural change. In doing so, it revealed its methodological utility in developing practical social theory. Additionally, we investigated the processes and strategies adopted to reduce the rate of fibrinolysis and to increase STEMI patients' access to primary percutaneous coronary intervention in Portugal. The Stent for Life initiative was successful in achieving these ends.

Figure 1 – The Morphogenetic Sequence



Source: Archer (1995, p. 82).

Table 1 – Interviews Carried Out

Interviewee	Date	Place where the interview was conducted	Length of the interview
SFL champion + a member of the SFL task force	February 7, 2014	Hospital Garcia da Orta, Almada, Portugal	1h30m
SFL national project coordinator	February 21, 2014	Researchers' university	1h20m
SFL national project coordinator	June 30, 2014	Researchers' university	1h20m
President of the Portuguese Emergency Medical Services (INEM)	July 24, 2014	Researchers' university	2h
SFL champion + a member of the SFL task force	November 13, 2014	Hospital Garcia da Orta, Almada, Portugal	1h40m
SFL national project coordinator	November 20, 2014	Researchers' university	1h20m
SFL champion	February 17, 2015	Hospital Garcia da Orta, Almada, Portugal	1h30m
Member of the SFL task force	April 23, 2015	Researchers' university	1h20m

Table 2 – Material and Cultural Structures in T1

Material Structures (Internal relations between objects)	Ideal / Cultural Structures (Theories, beliefs and writings which make certain truth claims)
Relations of internal necessity and complementarity (Archer, 1995) between ESC, EAPCI, EuroPCR, ESC Working Group on Acute Cardiac Care, Portuguese Society of Cardiology, APIC: ‘strategy of protection’	PPCI became the preferred treatment for patients with acute ST-segment elevation myocardial infarction (STEMI) (Widmsky <i>et al.</i> , 2010; Kristensen <i>et al.</i> , 2012)
Scant use of PPCI in Southern European and Balkan countries (Laut <i>et al.</i> , 2011)	ESC established guidelines for STEMI patients being treated with PPCI
Relations contingently linked and of complementarity between Portuguese NHS hospitals and INEM (Archer, 1995): Lack of communication, long patient delay / ‘strategy of opportunism’.	Portuguese population lacked information on the typical symptoms of myocardial infarction
Poor coordination between hospitals’ emergency services and cardio surgery units departments (Manchester screening system inappropriate)	Little awareness of the emergency call number (“112”)

Table 3 – SFL Portugal Situation in May 2011

Country Detail	Situation
Population	10,557.6 Million
Country surface area	92,090 km ²
GDP per capita	€16,686.3
Number of interventional cardiologists	70
Rate of AMI mortality	3.10%
Usage rate of PCI	63%
Usage rate of thrombolysis	43.50%
Rate of no reperfusion therapy	37.30%
PPCI per million	280
Percentage of PPCI in STEMI patients	19%
Number of cath labs	20
Number of 24/7 cath labs	19
Average distance to cath lab	150 km
Number of ambulances	493
Number of ambulances with electrocardiogram	77
Availability of helicopters	Yes
Percentage of patients that call EMS	23%

Source: Portugal SFL National Project Coordinator.

Table 4 – SFL Portugal Situation in June 2014

Country Detail	Situation
Population	10,427 Million
Country surface area	92,090 km ²
GDP per capita	€19,492
Number of interventional cardiologists	70
Rate of AMI mortality	2.42%
Usage rate of PCI	68%
Usage rate of thrombolysis	25%
Rate of no reperfusion therapy	7%
PPCI per million	337
Percentage of PPCI in STEMI patients	68%
Number of cath labs	19
Number of 24/7 cath labs	18
Average distance to cath lab	150 Km
Number of ambulances	550
Number of ambulances with ECG	87
Availability of helicopters	Yes
Percentage of patients that call EMS	35.4%

Source: Portugal SFL National Project Coordinator.

Table 5 – Material and Cultural Structures in T4

Material Structures (Internal relations between objects)	Ideal / Cultural Structures (Theories, beliefs and writings which make certain truth claims)
Better communication between INEM and PPCI hospitals: there are more INEM ambulances equipped with telemetry and facilities to transfer electrocardiograms to hospitals (87 ambulances in 2014 against 77 in 2011). Inter-hospital secondary transport has also improved.	Portuguese population became more knowledgeable about the typical symptoms of myocardial infarction and the importance of acting quickly: 68% of PPCI in STEMI patients in 2014 vs. 19% in 2011.
More coordination between hospitals' emergency services and cardiology departments: regular meetings in hospitals between emergency services and cardio surgery units were organised to overcome coordination problems .	Increase in awareness of the emergency call number: 35.4% of patients called "112" vs. 23% in 2011.

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¹ This contrasts with Giddens' duality of structure, which holds structure and agency as mutually constitutive, precluding any examination of their interplay and of the effects of one upon the other.

² This refers to time between presentation at the PPCI hospital (i.e., a hospital with PPCI facilities) and use of first device in the culprit artery (Pereira *et al.*, 2014).

³ That is the official annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI).

⁴ The number of countries involved in the SFL increased to nine at the end of 2010, after Egypt, Italy, and Romania decided to adhere to the SFL. Furthermore, in 2012 Bosnia and Herzegovina and Ukraine joined the initiative; also, in 2013 Cyprus decided to become involved in the SFL.

⁵ Patient delay is defined as the time between symptom onset and first medical contact (FMC) (Pereira *et al.*, 2014).

⁶ The Manchester screening system was implemented in Portuguese hospitals at the beginning of the 2000s and aims to classify the severity of patients in emergency services.

⁷ APIC is a professional association of the Portuguese Society of Cardiology that aims to study and promote scientific activities related to medical, surgical, technological, and organisational aspects of cardiovascular intervention. Dr. Pereira became its general secretary and later, in 2012, its president.

⁸ The organisation of the Portuguese health system is based upon the division of the country into five regions (Lisbon and Tagus Valley, North, Centre, Alentejo and Algarve).

⁹ The national public campaign of "Act now. Save a Life" developed by Dr. Pereira received over two hours of coverage on three national television channels in eight months.