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European School of Molecular Medicine

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Thesis Title

From consent to choice: the ethics of empowerment-based reforms

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Abstract of the thesis

The aim of my thesis is twofold. First, I focus on the controversies arising from the renegotiations of patienthood and citizenship entailed in what I call ‘empowerment-based reforms’ (EBRs). What I define as EBRs will have in fact different implications for the various stakeholders involved in their development and implementation. *Empowered* citizens within EBRs will have access to (and will be required to manage) an unprecedented amount of information regarding their health conditions. Factors such as genetic and biological makeup, life-style behaviours and environmental exposures will be increasingly used (by both citizens and professionals) to identify treatment options, to target developing diseases, and to adopt preventive measures for future illnesses. Among the effects that this personalising vision of healthcare is likely to foster, it is thus worth emphasizing how the nature and scope of individual *responsibility* for health will be affected by this paradigm shift, and how this future scenario can be made an ethically desirable one. In my thesis, I therefore identify the range of normative exercises entailed in EBRs, and I present a normative analysis of empowerment aiming at highlighting the distinctive ethical aspects of this approach.

Second, the goal of my thesis is to explore how the normative theorization of empowerment proposed above can accommodate one of the most pressing societal implications of epigenomics. Namely, its burdening of individual responsibility for health. On the one hand, I argue that novel approaches to prevention, diagnosis and treatment brought about by epigenomics are a fundamental tenet of the personalization project at the basis of what I call EBRs. In this respect, epigenome-based healthcare is thus likely to foster controversies similar to other epistemic endeavours of personalized medicine (e.g. genomics, metabolomics, pharmacogenomics), which can be addressed from the normative premises of empowerment. On the other, I maintain that concerns arising from the translation of epigenomics into healthcare practice should be poised with its promise to make increasingly visible the ‘contextual nature’ of health (i.e. tracing the mechanistic interaction between lifestyle, living conditions and individual health). Rather than limiting societal appraisal of

epigenomics to the danger of burdening individual responsibility for health, I argue that epigenetic knowledge may become pivotal in fleshing out social and environmental influences inherently affecting individual health. Sufficiently valid, reliable and actionable epigenetic knowledge may in fact orient individual choice across the spectrum of environmental and lifestyle exposures determining health, thus championing epigenomics with the potential of serving the *empowering* aims fleshed out throughout this work.

The road connecting the constitution of an empowered citizenship in healthcare, and the societal appraisal of epigenomics can be regarded as a two-way road. There is in fact a possibility that empowerment and epigenomics may respectively shape their normative and epistemic dimensions in the future of healthcare. It is thus towards the identification of the possible challenges and opportunities that this synergy may bring about that the theoretical attention of this work is devoted.

How could anything originate out of its opposite? […] [I]t might be even possible that what constitute the value of these good and revered things is precisely that they are insidiously related, tied to, and involved with these wicked, seemingly opposite things – maybe even one with them in essence. Maybe!

(F. Nietzsche, Beyond Good and Evil, §2)

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Introduction

Contemporary biomedicine is widely regarded as heralding a number of revolutions. The advancements of the life sciences disrupt the boundaries between basic biology and medicine. Revolutionary (bio)technologies promise the development of a unifying molecular language, under which investigating one's biological make-up is increasingly indistinguishable from its direct application in the understanding, classification and management of many health conditions (Nowotny and Testa 2011). This change of perspective in medicine, I shall say, is the first *epistemological* revolution of modern biomedicine, where the understanding of the body and its illness get embedded in the style of thought of molecular biologists (Hacking 1992). From the rise of reproductive biotechnologies, to genetic testing, stem-cell therapies and the emergence of ICT-based tools for genome-wide analysis, the dynamic development of molecular discoveries opens up new perspectives over for the comprehensive management of health conditions. Rather than being enmeshed with the scale of tissues, organs and organ systems, medicine is increasingly imbued with a molecular topography of genes, alleles, proteins and epi-genes – to name a few – that shapes medical judgement and intervention. In doing so, this epistemological revolution also fuels the assemblage of novel *technological* platforms for more personalised, molecular and effective care (Garraway and Lander 2013). This is a second revolutionary thread in modern biomedicine, which emphasizes the technological drive required for the accomplishment of the epistemic aims of molecular medicine outlined above. From the strive to reduce sequencing costs and to optimize bio-computational analysis of whole-genome data, to the search for cell-reprogramming standardization and marketability, the first two revolutions (i.e. the epistemological and the technological) intermingle one with another, and mutually support the achievement of their respective goals (Keating and Cambrosio 2003).

By no means, however, the molecular and digital leap forward in medicine can be considered as a solely epistemological and technological one. Rather, molecular medical technologies are also technologies of life – of how we make sense of it. This *ontological*, third revolution points to the reconfiguration of the vital process itself, which happens in the unravelling of the molecular knowledge and its applications. The technical and the epistemological reconfigure our identity as human beings, they turn what was previously regarded as the natural working of the genetic code – the intangible code of life – into the *possibility* of changing and improving it (Harris 2007). This new alignment of intersecting technologies and biological understandings goes as far as putting into the remit of human agency, according to some authors, the freedom to intervene on and modify its own nature (Habermas 2003). This means that this change of perspective in the understanding of what we are "by nature" triggers also a fourth strand of revolutionary thinking. Advanced technological biomedicine challenges the *political* and *moral* categories governing the outset of the twenty-first century (Rose 2007). In configuring a sophisticated diagnostic and therapeutic repertoire of gene sequences, cell lines and big data, medicine demands a renegotiation of individual, community and state roles in realizing the future of individualized and personal care become reality. Biological notions of patienthood become pivotal in *activating* citizenship projects, whereby the demand to plunge into the molecular roots of 'our own diseases' becomes an imperative to participate to governmental regimes of medicine (Rose and Novas 2004). A new morality of active and informed patient citizenship emerges from the need to act responsibly upon the wealth of knowledge of molecular medicine, and calls for the development of political techniques that can *empower* individual agency to maximise its potential benefits.

In a nutshell, the multiple ways in which all of these different revolutions (i.e. epistemological, technological, ontological and political) intermingle constitute what has been called a new molecular *biopolitics* (Rose 2007). Or, if we wanted to be cautious about historical claims, these molecular revolutions most likely build upon and stem from the past developments of biopolitical regimes (Foucault 1973). The interrelation between these four "revolutions" leverages in fact past renegotiations of concepts such as medicine, biology, reproduction, care, risk, patient, healthy individual, citizen (and many others) to recast them under the mutations occurring in the age of 'omics technologies and the personalization of medicine (Chadwick 2013).

In this thesis, I do not map the various interactions among ontological, epistemological, technological and political domains of contemporary biopolitics. Rather, I focus and isolate the challenges attached to two of the technologies underlying its innovation: namely, the political discourse of *empowerment* in contemporary healthcare policy-making, and the biomedical platform of *epigenomics* in the rise of personalised medicine. In sacrificing the breadth of approaching the molecular biopolitics in the entirety of its intertwined dimensions, I hope my analysis gains depth on the respective challenges raised by these two endeavours, and on the potential reinforcement we can envisage between them.

The reasons to focus specifically on empowerment *and* epigenomics are in fact manifold. First, the concept of empowerment plays a pivotal role in political discourses of healthcare reforms (Colombo et al. 2012). Empowerment strategies are widely regarded as a suitable framework to accomplish the goals of contemporary personalised biomedicine (European Science Foundation 2012). The promise of empowerment in activating the citizenship project of responsibility to act upon (and be liable for not doing so) the richness of information provided by molecular biotechnologies for health can, in other words, deliver the shift *from consent to choice* envisaged by the biopolitical regime of the twenty-first century. However, the language of empowerment is an extremely controversial one. Besides lacking definitional precision, which represents for some scholars a good reason for avoiding the use of this term (Salmon and Hall 2004), the discourse of empowerment fosters several ethical controversies that deserve careful analytical scrutiny. As shown in Part 1 of the thesis, what needs to be clarified is whether empowering citizens has an intrinsic value (e.g. it is the right thing to do for reasons of democracy, freedom and justice), an instrumental value (e.g. allows policy choices to be coproduced with publics in ways that authentically embody diverse health outcomes, values and meanings), or is animated just by economic motivations (e.g. it fosters social responsibilities for the management and improvement of health with consequent reduction of national health costs).

Second, the discourse of epigenomics is a promising and emerging field of inquiry in contemporary biomedicine. Studying the epigenetic roots of health and disease is expected to bring into the vision of personalised medicine the missing piece in the aetiological puzzle of most common diseases (Mill and Heijmans 2013). The language of epigenomics shows, measures, and (promises to) make(s) sense of the plastic responses of our genome to its environment broadly conceived (from lifestyles, to occupational exposures, pollution, parental care, etc.). In doing so, epigenomics shows how transient and dynamic the interplay between genes and experience, biology and biography is. And consequently, it evokes an imaginary of reversibility and responsibility to safeguard one's epigenome. The genome becomes, through the rise of epigenomics, an eminently malleable developmental resource (Moss 2004), damaged and protected by individual agency (Meloni and Testa 2014). These visions and expectations fostered by epigenetic knowledge are beginning to circulate in society, though they have only just begun to be investigated in their implications (Landecker and Panofsky 2013). The societal aspects of epigenomics are still a widely uncharted territory (Rothstein 2013), and demand a thorough philosophical and sociological appraisal to which Part 2 of this thesis is dedicated.

But there is more than the need of both scrutinizing the unwanted consequences of empowerment, and anticipating the emerging societal challenges of epigenomics, at the basis of the focus of this thesis. What will be (hopefully) clear at the end of this work is that the two trajectories of empowerment and epigenomics can mutually reinforce and forge their importance in the biopolitics of the twenty-first century (Rose 2007). The paradigm-shift in the understanding of the social and biological roots of health and disease outlined by epigenomics may in fact help accomplish the *empowering* social program I defend throughout this work. Different scholars have already emphasized how epigenomics intersects with research on and regulation of our social life (Dupras et al. 2012, Landecker and Panofsky 2013). To this recognition, my thesis adds that valid, reliable and actionable epigenetic knowledge may provide comprehensive information on the limitations of one's power to (i) remedy to health problems, and (ii) resist to the effects of powerful social determinants of health over material and societal injustices (Marmot and Wilkinson 2003, World Health Organization 2013). This is, in essence, *the* empowering step in the social trajectory of epigenomics envisaged and problematized by my thesis, which constitutes also a cogent reason to focus on empowerment *and* epigenomics together.

Building upon these premises, *Part 1* of this work focuses on an ethical scrutiny of the discourse of empowerment in recent healthcare policy-making. Chapter 1 starts from a historical analysis of what I call EBRs in recent policy-making literature (see *infra* Chapter 1). Here, I note how a "new wave" of empowerment in healthcare policy and reforms has produced a shift in the substantive foundations of empowerment. The emancipatory discourse of *control* and liberation from social oppression traditionally associated to the concept (Freire 1972, Tengland 2008) has recently become a discourse allegedly aimed at a renegotiation of power relationships in healthcare through devolutions of responsibility for health. Moving on from this descriptive analysis, I then argue that this paradigm-shift in the values at the basis of empowerment is likely to generate some ethical controversies. In particular, I discuss issues related to *paternalism* in EBRs (see *infra* Chapter 2), to what I call the 'charge of *healthism*' (see *infra* Chapter 3), and to the potential unwanted consequences of different evaluations of *responsibility* within this context (see *infra* Chapter 4). Finally, I also address the methodological issue of how to import the distinctive ethical aspects of empowerment emerging from my analysis in the construction of valid instruments for the evaluation of its effectiveness (see *infra* Chapter 5).

Part 2 of the thesis explores instead the contribution of epigenomics to the political project of personalised medicine. Accordingly, I start from a review (see *infra* Chapter 6) of the impact of epigenetic science on the understanding, management and treatment of three common disease areas (i.e. cardiovascular diseases, neuropsychiatric disorders, and cancer). The flip side of the monumental shift in the understanding of the *plasticity* of both disease aetiology and health outcomes promised by epigenomics, I argue, is the creation of an imaginary of individual and collective *responsibilities* to protect one's epigenome and consequently one's health (Hedlund 2012, Chadwick and O'Connor 2013). Building upon this recognition, I finally problematize in Chapter 7 the emerging notion of 'epigenetic responsibility' from two main perspectives. On the one hand, I show how the normative understanding of empowerment proposed in Part 1 could accommodate the burdening of individual responsibility for health attached to the societal impact of epigenomics (Hedlund 2012, Chadwick and O'Connor 2013). On the other, I also turn to the potential synergies between my theorization of empowerment and the promises of epigenomics, which could indeed render the emerging style of thought of epigenomic medicine a genuine *empowering technology*.

This thesis may, in the end, solve none of the current political and social struggles attached both to epigenomics and empowerment. Yet, I hope the analysis I present may clear up the ideas of those who are willing to delve into the liberatory potential of intersecting these two thought-provoking endeavours.

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Part 1

Chapter 1. Empowerment-based reforms (EBRs): a "new wave" of empowerment thinking

Introduction

Contemporary healthcare-policy making in Europe[1] is largely dominated by what has been announced as "the patient revolution" (Richards et al. 2013). An increasing emphasis is currently being put on the necessity to open-up the practice of medicine to patient perspective and involvement, both with regard to primary healthcare services (Barranco Morris and Morris 2008, Entwistle and Watt 2013), and the public health perspective (Cribb 2005). Within this broader political discourse, a central role is played by the notion of *empowerment*. Frequently, this term heralds the promise of a holistic, individualized, and participatory vision of medicine (Fackler and McGuire 2010) that will allegedly guide the future of medicine. Resorting to the empowerment strategies in the context of policy-making is regarded as an ethical *panacea*, fostering a renegotiation of power relationships within the healthcare system that opens up healthcare governance to the perspective of non-experts (Colombo et al. 2012). Throughout this work, I will label all policy documents that argue for a putative empowering shift in healthcare "Empowerment-based Reforms" (henceforth EBRs).

As we will see, many examples of EBRs can be found in the European context both at the level of national and supra-national policy-making. Starting from this documentary evidence, the aim of this chapter is to scrutinize different historically situated sociotechnical imaginaries (Jasanoff and Kim 2009, Jasanoff and Kim 2013) created by EBRs, and to identify the ethical tensions generated by their uncritical acceptance of empowerment as a flagship value for future healthcare. I take the notion of socio-technical imaginary to describe how different EBRs envisage a future for national and/or supra-national healthcare systems, which

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[1] As shown by the discourse analysis of policy documents constituting the core aim of this chapter, what Richards and colleagues (2013) call "the patient revolution" mostly applies to the European context. This means that my scrutiny of Empowerment-based reforms is not meant to convey any claim as to the ethical controversies arising from similar healthcare reform strategies outside the European context. Rather, I am fully aware that the ethical framework developed through this thesis may not be able to capture the specificities of local contexts outside Europe, thus rendering it unsuitable for policy formulation at the global level (Mackintosh and Koivusalo 2005).

not only constitutes a vision of a number of achievable social benefits, but also produces a number of goals, meanings, norms and interpretations of the roles that actors should play for their attainment. As we will see in the remaining of this chapter, all EBRs *imagine* different renegotiations of power between the system and the clients[2], the professional and the patient, and compel each of these actors to subscribe to a new meaning and value assigned to their contribution to the success of EBRs.

Accordingly, the first section of this chapter will focus on the different *conceptions* of empowerment that are endorsed – and prospectively enforced – by numerous examples of EBRs (World Health Organization 1978, 1986, Great Britain 2004a, 2004b, 2004c, 2005, 2008, 2010a, 2010b, 2010c, 2010d, 2010e, European Commission 2007, 2011, 2013, European Science Foundation 2012). Ranging from reform proposals of national healthcare systems, to disease-based healthcare policies and long-term visions for the future of healthcare, all of EBRs share the intent of yielding new relationships between healthcare systems and citizens. Specifically, I highlight how empowering structures and empowered agencies EBRs envisage have profoundly changed in their historical development. With regard to this, I identify one striking difference between current uses of empowerment and its original "outbreak". Namely that, in the last decade, the focus of the approach has shifted from the community-based and emancipatory goals of its original proponents (Freire 1972, Tengland 2008), towards an emphasis put on individual responsibility for health. It is this paradigm shift, I argue, that has recently associated the concept with a bipartisan (Perkins 1995), neo-liberal and consumerist view of healthcare agency (McGregor 2001, Veitch 2010).

The second section argues instead that the tensions between the early empowerment discourse and its consumerist "new wave" is at the basis of the scepticism currently surrounding empowerment in healthcare policy-making (Covolo et al. 2012, Woodall et al.

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[2] Throughout this work, I will be using the formulas 'healthcare client', or 'client' to signify no more than the kind of individuals who make use of healthcare services without necessarily having been diagnosed for any condition. A client is to me an individual who seeks the advice of her physician, or other qualified healthcare professionals, without experiencing any particular symptom or distress. This is, to my view, what distinguishes a 'client' from a 'patient'. Paradigmatically, a client is an individual who undergoes genetic susceptibility testing, and identifies health-related risks that can be ameliorated through lifestyle. I am well aware that the term may be charged with a consumerist interpretation of the role of citizens in medicine (Harvey 2010). Yet, my use of the term does not necessarily intend to comply with this interpretation.

2012, Christens 2013). In addition, I also show how the distinct notions of empowerment at the basis of EBRs, which envisage different renegotiations of power relationships among healthcare actors (Veitch 2010), can generate some ethical tensions in their implementation. Starting from this recognition, I identify three fundamental substantive domains of controversy within the political project of EBRs. I show that the concept of empowerment, within this context, may generate ethical concerns because of its commitment to (i) a renegotiation of the power relationship between professionals, or more generally the healthcare system and the citizen patient; (ii) the achievement of individual health goals (iii) the allocation of responsibility for health on citizenship. Whether or not the shift to empowerment-centred healthcare is something ethically desirable, I conclude, will very much depend on our capacity to clarify the normative exercises that characterise such *bundle* of values at the basis of EBRs. The following three chapters of Part 1 of the thesis are then dedicated to an analysis of each of these substantive domains of EBRs.

EBRs and the "new wave" of empowerment thinking

Moving healthcare systems with our times, scholars and policy-makers argue, means recognising that some empowering steps are required when advancing a proposal for reforming them (Segal 1998, Veitch 2010, Colombo et al. 2012). First and foremost, devolving power to citizenry could produce a shift from 'reactive' to participatory, proactive, pre-emptive and preventive approaches to medicine (Auffray et al. 2010, European Science Foundation 2012). Chronic and non-communicable diseases, this line of reasoning goes, are by far the biggest killers in high-income regions of the globe (World Health organization 2010), and are vastly dependent on risk factors related to individual lifestyle and biological make-up. As these information become more and more integrated and clinically relevant for the development of individually-tailored life-long monitoring of health, emphasis must therefore shy away from patients (i.e. those who already display symptoms) towards *empowered* citizens taking control and action to manage their health and prevent diseases to develop over the life course (Barry and Edgman-Levitan 2012). Second, the empowerment of healthcare clients may foster a culture of positive consumerism in medicine. Citizens may become empowered enough to act upon and integrate information from multiple sources (e.g. genomic profiling, epigenomics, proteomics, metabolomics data), so as to be able to choose among a range of services provided by the healthcare system (Segal 1998, European Commission 2013). Third, empowering citizens is bestowed with the capacity to decentralize authority for public decision-making on the healthcare system (Perkins 1995, Veitch 2010, Colombo et al. 2012), thus rendering the preferences and opinions of all actors the means of governing healthcare in a more transparent and accountable way. Roughly put, the commitment to empowerment is widely regarded as thinking ahead the roles of citizenry and experts for the future of medicine, as well as producing the benefit of putting individuals – being patients or more broadly *citizens* – at the heart of the healthcare system (Great Britain 2004a).

The recognition of empowerment as a flagship value for achieving this wide range of social and political objectives is not surprising. With its origins in liberatory pedagogy, social psychology, mental health and health promotion (Freire 1972, Rappaport 1987, Wallerstein and Bernstein 1988, Rodwell 1996, Laverack and Labontè 2000), the concept is traditionally associated to the emancipatory ability of gaining mastery over an intended state of affairs. Specifically, the emancipatory ability entailed in empowerment has always been associated with the uncontroversial goal of developing the *power to* control one's life or health (Wallerstein 1992), while at the same time liberating the subject from exercises of *power over* herself (Wartenberg 1990, Buchanan 2000, Laverack 2005). 'Power-over' represented, in the minds of proponents of empowerment, a coercive or ideological power that keeps groups marginalized, whereas 'power-to' was instead the power to influence change with others (Labonte and Laverack 2008). The notion of empowerment used to be equated therefore with two different kinds of processes and goals (Tengland 2008). On the one hand, empowerment was the *goal* of a process of liberation conferring individuals the capacity to (power to) give rise to a desired outcome. On the other hand, empowerment was also *the process* of developing the goal above by transforming social configurations, liberating individuals from influences over (power over) themselves through advocacy and community engagement.

It is because of these two different dimensions of empowerment that the approach is often considered as an ethical *panacea* in health promotion, especially in the case of community-based and marginalised groups. Empowerment, understood as such, is widely regarded as a *third way* in public health avoiding the pitfalls of both focusing only on individual liberty (as freedom from interference in personal matters such as health), and state intervention for the benefit of both individual and community health (Taylor and Hawley 2006, Tengland 2012). Radical educationalists in the empowerment field subvert the dichotomy between freedom to be left alone with regard to decisions concerning health, and the importance of collective action to improve people's health conditions. Rather, they entertain the idea that freedom or self-determination with regard to health concerns the powers (in the two meanings above) that we have over ourselves, which manifest as a capacity to affect and transform our behaviours in the community in which we live (Tengland 2012). A mere focus on individual freedom does not suffice, in the minds of the proponents of empowerment, to produce either health benefits or to respect individual self-determination with regard to health matters. And the same applies to top-down intervention of the state and healthcare authorities that could serve only the purpose of generating power-to control one's health, without challenging the structures of power-over individuals. Quite the contrary, health promotion is deemed achievable through intervention in the domain of communities, organizations and social arrangements, where a gain of power at the *interpersonal* level (i.e. the capacity to affect the social environment) may generate genuine positive health changes at the *intrapersonal* level (i.e. enhance our freedom with regard to health-related matters) (Minkler 1999).

This emphasis upon the social domains of freedom with regard to one's health affirms, in other words, the importance of promoting individual sovereignty, while at the same time recognising the role of the state as a supporter or facilitator in making the individual seize mastery over her own health. Starting from this recognition, it is not difficult to see the importance that the notion of *control* plays in the definition of empowerment in the academic literature (Rappaport 1987, Wallerstein and Bernstein 1988, Wallerstein 1992, Perkins 1995, Laverack 2005, Tengland 2007, 2008). On the one hand, being in a *state* of empowerment is better specified as "an ability […] that the individual develops to control her own life" (Tengland 2008, 82) and health. On the other, empowerment refers also to the *process* that is likely to bring about the 'state of being in control of one's life', and entails a specific understanding of the relationship between a client and a professional. Empowerment is a transformation of social configurations (Freire 1972), liberating individuals from power structures and professional expertise. Control assumes therefore also the second meaning of resisting negative influence from experts/professionals in the process of achieving an empowerment state (Tengland 2007, 2008).

Otherwise stated, the two aspects of the notion of empowerment as both a state and the process map onto two different declensions of the notion of control (i.e. control as ability, and control over the process that leads to the ability). This is, for instance, evident in the first deployment of empowerment at the level of policies in the "Declaration of Alma-Ata" (World Health Organization 1978). In this first example of EBR[3], the concept is bestowed the capacity to address existing inequalities in the health status of the people (particularly between developed and developing countries), by representing an approach that:

> "requires and promotes maximum community and individual self-reliance and participation in the planning, organization, operation and control of primary health care, making fullest use of local, national and other available resources; and to this end develops through appropriate education the ability of communities to participate" (World Health Organization 1978, Art. VII-5, emphasis added).

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[3] It may look odd to the reader that I hereby call EBRs also documents such as the "Declaration of Alma-Ata" (World Health Organization 1978), or the "Ottawa Charter for Health Promotion" (World Health Organization 1986). However the reason for this is that, even though both of them cannot be immediately defined as reform proposals, it is implicit that their nature of global strategies for healthcare is meant to identify the key health-related goals to be attained through national policies and reforms. Though not being strictly speaking reforms, these documents had the potential to trigger reform processes among state members of the World Health Organization, and can therefore be labelled EBRs.

This quote suggests that empowerment approaches in healthcare policy-making ought to operate on a *continuum* from the level of the individual to the community and organizational levels (Laverack 2007). But most importantly it shows that the concept, in its early use within the policy-making literature, was framed as a resource to counter oppression and injustice (Tengland 2008, Woodall et al. 2012), and was meant as a broader political and social process by which groups and communities seize control (in the two senses above) over their health (Rappaport 1987, Segal 1998). Empowerment processes need, in other words, to be oriented both toward challenging oppressive structures as well as nurturing relationships that enable people to strengthen control of their own lives for the benefit of all (Restrepo 2000).

It is important to stress here the element of social liberation characterising the approach at its outset. The distinctive feature of early EBRs is in fact that the notion of *control* introduced above requires also a specific view of what kind of individual health goals ought to be achieved through empowerment. As exemplified by the "Ottawa Charter for Health Promotion" (World Health Organization 1986), a major milestone in the 20th century of the field of public health, empowerment was originally regarded as a strategy to promote individual mastery and ownership of health, which is understood as a general state of wellbeing. Rather than being instrumental to the achievement of health goals predetermined by the system, empowerment is here regarded as promoting a liberation of the individual in healthcare, which is epitomized by the formula of setting priorities for achieving *health* as a broader physical, mental and social state (World Health Organization 1948):

> Health promotion is the process of enabling people to increase control over, and to improve, their health. To reach a state of complete physical, mental and social well-being, [health promotion] works through concrete and effective community action in setting priorities, making decisions, planning strategies and implementing them to achieve better health. At the heart of this process is the empowerment of communities, their ownership and control of their own endeavours and destinies (World Health Organization 1986).

Yet, in the last decade the focus of empowerment approaches within health promotion and policy-making appears to have radically moved from the objective of enabling the oppressed to achieve their own health goals, towards an emphasis on individual choice and responsibility for health (Perkins 1995, Christens 2013). A new interpretation of the concept as a neo-liberal ideology has been inaugurated, which has made the approach much more appealing to recent healthcare policy-making (Colombo et al. 2012, Covolo et al. 2012). Empowerment programs and policies are currently very popular in political discourses, and have proliferated in the last few years by receiving an uncommon bipartisan support. On the one hand, conservatives view the approach as fostering a culture of private voluntarism in healthcare that reduces the role and importance of state supervision with regard to health-related decision-making. On the other, new labour and socio-democrat politicians see instead EBRs as renegotiating public support for citizens with regard to their health. Empowerment is now a buzz word for implementing the political objectives of (i) increased individual responsibility for health-related decision-making, (ii) provision of sound information, and (iii) enhanced control over the healthcare system. In a nutshell, this "new wave" of empowerment narrows down its goals to the provision of skills and opportunities, at the individual level, useful to a *proactive and individualistic* exercise of health-related decision-making, and purges the approach of any commitment to addressing health inequalities through community action[4].

The New Labour Interpretation of EBRs: breaking with the tradition

The first clear-cut example of this "new wave" of EBRs is represented by the proposals for reforming the UK National Health Service (NHS) put forward by the New Labour governments (Great Britain 2004a, 2004b, 2004c, 2005, 2008). Here, the empowerment approach is expected to foster an active role on the side of citizens "choosing which provider treats them and controlling healthcare decisions" (Great Britain 2004a, 79). Rather than being

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[4] Consistent with, although not always explicit in this view is the idea that empowerment can occur even without fostering any change at the community level (Laverack 2007, Wallerstein 2006), thus abandoning the general commitment of the approach to addressing the social context and determinants affecting people's health (Marmot et al. 2010).

committed to the radical overtones of the original approach, here empowerment is bestowed the capacity to update the relationship between the state and the citizenry in line with the new culture of consumerist individualism characterising contemporary British public life (Thorpe 2010):

> Patients' desire for high-quality personalised care will drive the new system. Giving people greater personal choice will give them control over these issues, allowing patients to call the shots about the time and place of their care, and empowering them to personalise their care to ensure the quality and convenience that they want (Great Britain 2004a, 9).

The shift towards empowerment in healthcare is regarded, in the case of the New Labour EBRs, as part of a broader intent to establish an "entrepreneurial spirit in institutions, and a consumerist orientation in public life" (Thorpe 2010, 403). Health politics is here an instantiation of a new kind of public life, which draws from the decline of conventional and traditional 'nannying' state, and the necessity to encourage civic and social initiatives. Accordingly, empowerment is not anymore emphasized as a transformation of oppressive power structures that affect health. Rather, it is instrumentally valuable for providing citizens with the opportunity to influence public decision-making on the healthcare system *in partnership* with healthcare authorities. Social participation strategies within this context are not, in other words, meant to establish a strong link with social change and therefore with bottom-up community-based action and political processes. Quite the contrary, the New Labour EBRs are concerned with top-down development of health-related public policy, which aim at securing a range of options to individuals on which to exercise their choice in a market-like fashion (Veitch 2010). In the light of this recognition, it is by no means surprising that the emphasis of New Labour's EBRs falls heavily on individual *responsibility* rather than on "control" (World Health Organization 1978, 1986) for maintaining a chosen level of health, and running public services together with healthcare authorities. Once those in power set the range of options, it is up to the responsible citizens to take up the opportunity to manage her own health:

> Patients empowered in this way are more likely to take greater responsibility for their own health, and to dedicate their own time, effort and energy to solving their health problems. This partnership is especially important for those with long-term conditions and their carers. We must therefore continue to empower patients with greater choice, better information, and more control and influence (Great Britain 2008, 38).

The new-labour interpretation of empowerment strategies in healthcare inaugurates therefore the different discernment of the substantive foundations of the approach anticipated above. Or, I shall say, a "new wave" of empowerment thinking in healthcare policy-making. Rather than aiming at emancipating the worse-off with regard to their health, i.e. giving them a chance to pursue their own state of complete physical, mental and social well being (World Health Organization 1986), empowerment requires here taking up a number of responsibilities on the side of citizens. First, one kind of responsibility envisaged by these reforms can be described as a responsibility to choose (services, treatments, practitioners' advice) within the publicly funded healthcare system. Such a responsibility demands citizens to act as *consumers* (Veitch 2010, Curnutte and Testa 2012), and to select the preferred service among the ones provided by institutions. Second, it is worth noting how it is central to the success of this public health strategy not only that patients exercise choice with regard to what service they may require, but also that they provide feedback on the treatments received, the support of professionals, and the quality of their experience in the NHS. This means that, through the lens of New Labour EBRs, empowered patients and clients are responsible also for speaking up, for ensuring that their voice is heard in order for the system to function properly. Third, a manifest importance is also given to patients and citizens assuming a responsibility for the management of their health levels, this being a matter of changing their lifestyles in order to adopt healthier behaviours, or making "the *right choices* for themselves and their families" (Great Britain 2008, 39; emphasis added).

The numerous responsibilities yielded by New Labour EBRs do not pertain, however, only to the three kinds of responsibilities placed upon individuals described above. It is indeed also important to stress how they also instate a precise role and accountability for professionals. Although sometimes presented in the document as a *partnership* between lay citizens and healthcare professionals (Great Britain 2008, 38) healthcare staff is expected to play "a stronger role for clinical leadership and management throughout the NHS" (Great Britain 2008, 48) within the picture of New Labour EBRs. Quality of the services, these EBRs argue, "is improved by empowered patients and empowered professionals" altogether (Great Britain 2008, 48):

> If clinicians are to be held to account for the quality outcomes of the care that they deliver, then they can reasonably expect that they will have the powers to affect those outcomes. This means they must be empowered to set the direction for the services they deliver, to make decisions on resources, and *to make decisions on people* (Great Britain 2008, 64; emphasis added).

Changing towards an empowerment-based system requires therefore, according to New Labour EBRs, not only that greater freedom and responsibility is devolved to citizens. Rather, such a shift requires *leadership* (Great Britain 2008, 65) on the side of professionals to make individual citizens and patients meet the health-related expectations of the system of tomorrow. Redrawing the boundaries of medical and professional responsibility in this way fosters some ethical concerns, to which we will turn in the final section of this chapter. For the moment, it is however worth noting the contrast this understanding of empowerment creates with the original tone of the approach. As it appears evident from the quote above, the empowerment of healthcare professionals prospected by New Labour EBRs outlines a relationship between the roles of stakeholders in the system that does not lend itself to the shift in authority and legitimacy for which empowerment was traditionally evoked:

> Health promotion is carried out *by and with people, not on or to people.* It improves both the ability of individuals to take action, and the capacity of groups, organizations or communities to influence the determinants of health. Improving the capacity of communities for health promotion requires practical education, leadership training, and access to resources. Empowering individuals demands more consistent, reliable access to the decision-making process and the skills and knowledge essential to effect change (World Health Organization 1997; emphasis added).

Differently from the revival of Freire's theories (Freire 1972) on popular education and consciousness-raising epitomized by this quote from the Jakarta Declaration, New Labour EBRs do not support the egalitarian power linked to early uses of the concept of empowerment in policy-making. The idea of a social-action process that promotes participation and control of people (e.g. organizations, communities, marginalised groups) in solving health problems is instead diluted in an expert-led and informed consumption of healthcare services (Woodall et al. 2012). Empowerment does not imply here extending the degree of public involvement for the sake of putting the source of legitimacy in health-related decision-making onto the hands of the non-experts. Quite the contrary, the emphasis on *leadership* in New Labour EBRs supports the interpretation that no challenge to the distribution of power in the clinical encounter is actually demanded by these documents, thus rendering their use of the language of empowerment "a cloak under which powerful actors can obscure their continuing exercise of power" (Callaghan and Wistow 2006, 596).

To recapitulate, there can be little doubt about the sharp contrast in which New Labour EBRs and traditional understandings of empowerment stand. First, New Labour EBRs introduce the language of responsibility in the discourse of empowerment, as opposed to the traditional emphasis on control (Wallerstein 1992, Tengland 2008). Most prominently, however, the new wave of empowerment inaugurated by New Labours operates a thorough reconfiguration of the values behind empowering processes (Tengland 2007, 2008). The element of power-over (or lack thereof) in the approach is in fact overlooked by this interpretation. Empowerment is still, at least in its declared aims, letting the healthcare client, group or community have as much control (or responsibility) as possible over the processes they are involved in. Nevertheless, no implication as to the role of professionals to serve this goal of empowerment is drawn by New Labour EBRs. The approach does not entail a view of the professional-patient relationship (Tengland 2008), which is concerned with the restrictive effect that medical expertise may have on individual ability to control medical decision-making (Callaghan and Wistow 2006, Juengst et al. 2012). Or, to use the jargon of its theorists, empowerment does not compel here practitioners to change their paternalistic behaviours, and to redistribute the "unbalance of 'power'" between them and the client (Tengland 2008, 91). Quite the contrary, no change in the professional-patient power balance is demanded by New Labour EBRs, thus opening up a question as to how this interpretation can actually attain the empowering goals it endorses.

Conservative EBRs for the NHS: empowering (healthy) choices

The kind of reasoning on empowerment introduced by New Labour EBRs is even more forthright in the usage of the term in the conservatives' proposals for reforming the British NHS (Great Britain 2010a, 2010b, 2010c, 2010d, 2010e). The ambition of these documents is in fact much more explicit in determining the shift to empowerment in the politics of the NHS as a devolution of active responsibility on citizens and professionals:

> Our ambition is to once again make the NHS the envy of the world. Liberating the NHS - a blend of Conservative and Liberal Democrat ideas - sets out our plans to do this. First, patients will be at the heart of everything we do. So they will have more choice and control, helped by easy access to the information they need about the best GPs and hospitals. [...] Second, there will be a relentless focus on clinical outcomes. Success will be measured, not through bureaucratic process targets, but against results that really matter to patients – such as improving cancer and stroke survival rates. Third, we will empower health professionals. Doctors and nurses must to be able to use their professional judgement about what is right for

> patients. We will support this by giving frontline staff more control. Healthcare will be run from the bottom up, with ownership and decision-making in the hands of professionals and patients (Great Britain 2010a, 1).

Through the endorsement of empowerment strategies, conservative EBRs appear to consolidate the devolution of governmental power into the social and the public firstly introduced by New Labours. *Equity and Excellence* (Great Britain 2010a), the strategy for the NHS proposed by the alliance between Tories and Liberal-Democrats, could thus be read as further instating the newly established tenets of empowerment that we encountered in its New Labour interpretation. Also here it is not difficult to see how the discourse of empowerment is bestowed the capacity to allocate a "shared responsibility" (Great Britain 2010a, 21) for using effectively healthcare services and improving citizens' involvement in decision-making. Furthermore, resorting to empowerment is again presented as a political response to sweeping social changes towards increased individualism, and to the need of rethinking the role of institutions in the governance of healthcare (Thorpe 2010). The main aim of conservative EBRs is, in other words, to "empower local leadership and encourage wide responsibility across society to improve everyone's health and wellbeing, and tackle the wider factors that influence it" (Great Britain 2010e, 6). In doing so, the strategy for healthcare is meant to "reflect the Government's core values of freedom, fairness and responsibility" (Great Britain 2010e, 6), which compel the healthcare institutions to "treat capable, responsible and informed adults as adults" (Great Britain 2010e, 28).

It is worth noting at this stage of my analysis how the link between empowerment and responsibility recasts empowering processes as a transfer of health-related risk, accountability and liability from society to individuals, and how this contrasts sharply with the traditional emphasis of the approach on the political opportunities for freedom and self-determination with regard to health. Conservative EBRs put a strong emphasis on the idea that creating the right environment for people to take responsibility for their health is "the way to improve health and wellbeing" (Great Britain 2010e, 23), thus producing individual benefits and reducing costs for healthcare for taxpayers:

> In future, patients and carers will have far more clout and choice in the system; and as a result, the NHS will become more responsive to their needs and wishes. People want choice, and evidence at home and abroad shows that it improves quality. We are also clear that increasing patient choice is not a one-way street. In return for greater choice and control, patients should accept responsibility for the choices they make, concordance with treatment programmes and the implications for their lifestyle (Great Britain 2010a, 16).

Leveraging personal responsibility for achieving outcomes of care and maintaining acceptable health levels is – under conservative EBRs – an empowering process instrumental to health-related behaviour change (Tengland 2012). Empowerment does not aim here at helping people "gain greater control over decisions and actions affecting their health" (World Health Organization 1997), but rather is regarded as an effective strategy for fostering a change in individual habits towards healthier lifestyles (e.g. exercising more, eating better, drinking less, quit smoking, etc.). Differently from "Whitehall diktats and nannying about the way people should live", empowering citizens is in fact considered as giving the right tools to individuals and communities to exercise healthy choices and relieve themselves from suffering of severe lifestyle-driven ill health, as well as reducing costs for healthcare in the national budget. To this end, conservative EBRs also envisage mechanisms of "financial incentives to reward progress on improving health" in the general population (Great Britain 2010e, 2).

Besides the limitations identified by other critics as to the capacity of conservative EBRs to actually reduce healthcare expenditure in Britain (Asthana 2010, Walshe 2010), it is worth emphasizing how these documents further contribute to define new roles for patients, citizens and professionals engaged in an empowerment process. Apart from taking up the emphasis of New Labour EBRs on responsibility for both users and professionals to exercise greater personal choice for the functioning of the system, conservative EBRs move forward the reconfiguration of the fundamental tenets of the approach operated in its “new wave”. They compel empowerment to the specific constitution of a normative domain of responsibility for the achievement of health goals that are established by top-down political measures. Empowerment is not here a public health strategy for increasing equitable health through an enabling process (Laverack 2005). It does not concern addressing the social determinants of health in order to create the conditions for making healthy choices easier for individuals, especially among marginalised groups of our societies (Koelen and Lindström 2005). Rather, empowering citizens is, in the conservatives’ view, redistributing the onus of health across society, in order to ensure that people remain free from diseases, and make responsible decisions about their lifestyle.

Personalised Medicine in the EU: the pinnacle of EBRs

The most clear-cut example of a system instituted by EBRs is however the rise of ‘Personalised Medicine’ (henceforth PM) at the level of European policy-making (European Science Foundation 2012, Lehrach 2012, Sahlin and Hermeren 2012, Shapiro 2012, European Commission 2013). Indeed, it could be even argued that the “personalization project” – providing the right individual with the right therapy at the right time – is nothing more than the pinnacle of all the initiatives that so far I have labelled EBRs. By promising to provide the technological and biomedical platforms (from genomics to epigenomics, proteomics and stem-cell therapies) to pursue the individualization of therapies and preventive measures, PM can move forward the shift towards empowerment-based healthcare firstly prospected by EBRs above (Chadwick 2013). It is however worth noting here that the discourse of empowerment does not make its appearance at the European level only with the advent of PM. Quite the contrary, the value of citizens’ empowerment is already recognised as a core value of healthcare governance in the EU Health Strategy "Together for Health" (European Commission 2007), the reference document for reform actions to be undertaken at national and EU levels between 2007 and 2013:

> A core value is Citizens' Empowerment. Healthcare is becoming increasingly patient-centred and individualised, with the patient becoming an active subject rather than a mere object of healthcare. […] Community health policy must take citizens' and patients' rights as a key starting point. This includes participation in and influence on decision-making, as well as competences needed for wellbeing, including 'health literacy' (European Commission 2007, 4).

This document points to an intensive investment on community activity and empowerment in healthcare systems, which should have guided the governance of the Union towards an increasing involvement of various actors in its making. *Together for Health* compels all Member States, for the first time in European legislation, to pursue the engagement of various stakeholders, like healthcare providers and patients (e.g. European Patients' Forum and the European Public Health Alliance), in political decision-making on the healthcare system. As argued by Flear (2008), *Together for Health* represents therefore a turning point in the EU governance of healthcare, which firstly establishes the need to explore modalities of engagement and empowerment of "patients *qua* EU citizens" (Flear 2008, 872). Meaning that this document operates a paradigm shift in the political discourse of European citizenship with regard to health and healthcare. In considering the potential for political discourses of active involvement, *Together for Health* redirects in fact the European governance of health from the commitment to extending rights to access healthcare to all Europeans (Jenson 2007), towards the constitution of an EU *patient citizenship*[5] as participation to the making of its healthcare polity. No doubt, the discourse of empowerment is also here regarded as the key strategy for reshaping the contours of agency in healthcare across the Union. This point is also

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[5] Besides the reference to Flear's (2008) work on the different discernment of citizens' role in the EU healthcare governance, the notion of 'patient citizenship' presented here is indebted to the analytical concept of 'biological citizenship' developed by Rose and Novas (2005), and Rose (2007). My analysis of the constitution of EU citizenship, as distinctively linked to the creation of new roles and responsibilities for patients, has benefited from Rose and Novas' scrutiny of "citizenship projects that have linked their conceptions of citizens to beliefs about the biological existence of human beings" (2005: 440), and wishes to complement this view by pointing on the political discourses, such as empowerment, which also play a decisive role in the generative process of new contours of citizenship in contemporary healthcare. Besides coming to think of ourselves as citizens in terms of knowledge of our somatic individuality (Rose and Novas 2005), the concept of patient citizenship highlights the importance of the politically constructed beliefs and expectations about the empowered role assigned to patients and citizens in contemporary EU polity of healthcare. To the best of my knowledge, the notion of patient citizenship has not been used so far with the only exception of Rhodes et al. (2013) field study on individual perceptions of patients affected by Hepatitis C.

reemphasized in the current EU strategy for healthcare "Health for Growth", which will run from 2014 to 2020:

> The position of the patient should be strengthened to achieve better and safer health outcomes. Patients need to be empowered to manage their health and their healthcare more *pro-actively*. The transparency of healthcare activities and systems and the availability of information to patients should be optimised. Healthcare practices should be informed by feedback from and communication with patients. Support for Member States, patient organisations and stakeholders is essential and should be coordinated at EU level in order to effectively help patients and in particular those affected by rare diseases to benefit from cross border healthcare (European Commission 2011, 13; emphasis added).

It is against this background, I argue, that the advent of PM should be analysed. PM constitutes the fulfilment of a broader political endeavour characterised by an increasing discursive weight assigned to citizens' engagement and participation to the governance of healthcare. At the basis of this political generation of European patient citizenship, we find the language of empowerment in its own development and reconstitution in the new wave of EBRs. Thanks to PM, however, EU healthcare can finally leverage also another decisive discursive repertoire for the accomplishment of the political project of EBRs. Namely, PM provides also the *bio-technological* means to move away from a one-size-fits-all approach in medicine, towards services that are tailored and responsive to the needs and characteristics of individual citizens. The emphasis that PM puts on profiling, prevention, early detection, and tailored treatments could successfully rise to the empowerment project identified above in EBRs, both with respect to the social and scientific challenges characterising contemporary healthcare (Auffray et al. 2010, Shapiro 2012). On the one hand, PM is allegedly able to grant healthcare an appreciation of the biological variability in disease development and treatment responses across the general population, which is currently made visible (Nowtony and Testa 2011) by the life sciences. In this respect, PM is *empowering* because it accommodates scientific advancements in the understanding of individual features of disease and illness into the practice of healthcare. Treatment and prevention strategies are in fact increasingly characterised by a "molecular gaze" (Nowotny and Testa 2011), and demand the seamless integration of data from all the 'omics technologies (e.g. genomics, epigenomics, metabolomics, proteomics, etc.)[6] for the sake of "tailoring the right therapeutic strategy for the right person at the right time" (European Commission 2013, 5; see also: Hood et al. 2004). As argued by Nowotny and Testa (2011), this defining feature of molecular life sciences opens up a wide range of possibilities for understanding and manipulating individual biological makeup and health to an unprecedented extent. On the other, PM's focus on individual responsibility for health allegedly meets the social demands of (i) cost-effective models of healthcare provision made necessary by the huge impact of healthcare costs on national budgets (Frith 2012), and of (ii) a more inclusive approach to patient involvement in medical decision-making (Kuehn 2012). By advocating for the requirement, on the side of citizens, to partake to the healthcare process and to actively contribute to the achievement of the health outcomes established by its proponents, the emerging model of PM can finally produce the *empowered* patient citizens envisioned by the new wave of EBRs:

> Despite the assertion that medicine has always been personalised, it is clear that in many areas citizens have not felt that they are fully in control of the decisions made about their wellbeing. Personalised medicine could provide the means for citizens to exert more control over their health without having to rely directly on professional healthcare. […] This is a potentially empowering step for European citizens. The promise of empowerment, however, raises issues of health literacy, responsibility and access (European Science Foundation 2012, 17).

Despite the caution rightly expressed here by the European Science Foundation on the potential unwanted consequences of empowerment, it is worth emphasizing how the empowered role for citizens entailed by PM has acquired a completely different meaning from

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[6] The unique contribution of emerging epigenomic medicine to this endeavour will be analysed in Part 2 of the thesis. See *infra* Chapter 6 and Chapter 7.

the one it had at its onset in the 1970s and 1980s (Tengland 2008). A new "sociotechnical imaginary" (Jasanoff and Kim 2009, Jasanoff and Kim 2013) of a desirable and tangible future of individualized, more effective and inclusive medicine is now evoked by the concept. Empowerment at the pinnacle of its "new wave" in healthcare policy-making means first of all constructing the aspirations to translate huge investments in 'omics technologies into medical practice, and to leverage citizens' contribution to the success of this paradigm-shift. This is the main reason why the shift towards the language of responsibility, initiated by EBRs described above, fits perfectly with the currency of the approach in PM. Enhancing individual responsibilities for their health is in fact beneficial to the empowering project of PM in three main respects. First, empowerment ties individuals to obligations and liability as to their use of the unique resources provided by 'omics technologies (e.g. genomics, epigenomics, metabolomics, proteomics, etc.), and the sustainability of the whole system. In this respect, the empowered role assigned to citizens demands taking up responsibility to be in charge of health-related choices, to contribute to the fulfilment of the promise of increased potential for prevention of disease based upon biological make-up and monitoring of physiological status over the life course. Second, empowerment here means also fostering a culture of responsibility with regard to maintaining certain levels of health by enacting the richness of medical information provided by its multiple sources of biological data. Citizens who are willing to get the best out the endeavour of PM, might not only want to fully exercise their powers with regard to their health, but also to comply with tailored treatments once diseases have developed, or tailored prevention strategies based on their continuously updated biological profile. Finally, empowerment in PM means also redrawing the boundaries of medical and public responsibilities with regard to citizens' health. The empowering step, entailed in PM, of giving citizens greater responsibility for their own health has in fact the correlate effect of freeing professionals or the healthcare system from a degree of responsibility for citizens health, thus producing a retraction of social and individual professional obligations to support the lay in the management of its own health.

This can, in essence, be one of the reasons why the language of empowerment is gaining increasing currency in EU policy-making, to the extent that some scholars have cautioned its colonization of governance discourses (Covolo et al. 2012, Colombo et al. 2012). PM reinforces the primacy of empowerment as a suitable strategy for making future healthcare move with the times of increasing individualized care. As the quote below suggests, the "personalization project" (Chadwick 2013) requires an empowering shift in healthcare services, which demands citizens to take up similar responsibilities to the ones we identified above for EBRs above, and provides them with the right biomedical tools to achieve this goal:

> If appropriate solutions can be developed in this way, it is likely that the role of the state will shift from taking responsibility for individual health towards empowerment of citizens and their communities to take responsibility for their own health. However, this will require a genuine devolution of power and agency to the citizen (European Science Foundation 2012, 41)

The language of empowerment has thus a strategic importance for fostering activism by biological citizens (Rose and Novas 2005) in the EU, so that as patient citizens they are more able to discern and contribute to the way in which health will be governed in the near future. This recognition raises, however, some questions about the extent to which the empowerment of citizens entailed in PM, and more generally in EBRs, could be detrimental to those lacking adequate skills to become responsible for their health. Wide ranges of experts and policy-makers agree upon the benefits that PM can offer and the importance of paving the way to its implementation (Fackler and McGuire 2010). PM can, as the rhetoric goes, provide citizens with the opportunity to leave better lives and to gain a greater mastery or power over their health. It is however likely that this empowering process will come at some moral cost. Granting increased access to information and factors that determine individual health (e.g. genetic predispositions, epigenetic exposures, metabolomics profiling, etc.) could actually be a winning strategy to achieve an improvement of health within the general population, and a genuine devolution of power and agency to the citizens (European Science Foundation 2012). Yet, sufficient attention should be paid to social factors such as race, culture, socio-economic context and gender having an impact on the individual capacity to gain power with regard to health (European Science Foundation 2012). How to ensure therefore that these critical aspects of empowerment are given sufficient attention?

The need for a normative scrutiny of empowerment in EBRs

Clearly, the analysis of the "new wave" of EBRs above confirms the widespread conviction that the concept of empowerment has been extremely preeminent in discourses of healthcare reforms and policy-making in the last decade (Veitch 2010, Colombo et al. 2012). In addition, it also hints at the possibility that the current suspicion surrounding the concept (Covolo et al. 2012) may largely be due to a clash between two historically distinct empowerment discourses. What I showed so far supports in fact the view that the narrative of empowerment has come to acquire very different contours in its historical development. On the one hand, the idea behind the original outbreak of the concept was that individual choice could not be analysed as if occurring in a relational *vacuum* (Minkler 1999). Rather, individual behaviour and choice were regarded as the result of power structures embedding the individual and her capacity to make decisions, whose 'control' empowerment processes were compelled to address. On the other, the "new wave" of EBRs inaugurates instead a different narrative of empowerment, mainly defined as a shift in responsibility with regard to health and healthcare governance from the state (or healthcare institutions) to individual citizens. Starting from this recognition, it is much easier to recognise how the term empowerment has gradually attracted critical scrutiny as a noble, but double-edged ideal (Sandroff 2012). Devolving power into the hands of *individual* healthcare clients was deemed to be ethically sustainable in the original theoretical underpinnings of the approach (Feste and Anderson 1995, Wallerstein 2006), only if accompanied by a strong emphasis on individual action for the sake of social transformations, as well as on the social dimension of individual capacity for self-determination (Rappaport

1987, Minkler 1999): an element which is now widely overlooked by the "new wave" of empowerment thinking in healthcare.

Is there a homogeneous account of empowerment? A 'bundle view' of the concept

This recognition supports the conclusion that distinct substantive commitments are entailed in the recent "new wave" of empowerment and its original understandings. Consequently, it raises a question as to whether the ethical allure originally attached to the approach still persists in its "new wave". According to some authors, the differences identified above within the empowerment discourse support the view that the concept should be best understood as a dynamic (moral) concept, whose different interpretations stand along a *continuum* (Laverack 2005, 2007, Labonté and Laverack 2008). The new wave of empowerment and its original conceptualization, this line of reasoning goes, can be regarded as two instances of the same concept ranging from individual to social and collective action. Empowerment, under this account, is best conceived as a flexible and multi-purpose framework, rather than a precise political, social and ethical theory. Accordingly, this view regards the concept as having only a general normative content – i.e. promoting the positive value of power and control gains over health-related decision-making through capacity building processes (Laverack 2005) – which needs then to be tuned to the various levels and contexts of its application.

Needless to say, the 'continuum view' has the merit of emphasizing how the goals of empowerment can potentially be maximized both through a focus on individuals and communities (Christens 2013). In addition, if we applied this view to the analysis of EBRs above, we might easily conclude that the different meanings assigned to the concept are actually due to the different contexts in which current proponents of PM and radical educationalists in the 1970s' and 1980's operate(d). However, a main limitation of viewing empowerment as a continuum lies in the possibility that fundamentally different substantive and normative commitments may underlie different uses of the empowerment language. Otherwise stated, the linear interpretation of empowerment entailed in the *continuum* (Labonté and Laverack 2008) may conceal the distinct substantive commitments at the basis of its different uses, and consequently obscure potentially divergent ethical evaluation of their outcomes.

For this reason, I argue that the definitional diversity of empowerment can be better captured through a different analogy that grasps the heterogeneous substantive and normative content of the concept. What I maintain is that evaluative commitments behind empowerment are best conceived as a *bundle* of different entitlements. Very much like in the case of other concepts (e.g. "self" in Hume 2012, or "property" in Hoppe 2009), the prescriptive dimensions of empowerment cannot be in fact straightforwardly identified, due to the variety of uses of the word. As we have seen above, the goals and the context of a given EBR could require different actions on the side of the agents involved, or simply be defined in very different ways. This means that a number of distinct entitlements may be part of the substantive content of a given notion of empowerment grounding an EBR. Or, if we put it in the words of the *bundle* analogy, different *sticks* can be designated for the sake of making up the bundle of values to be promoted for empowerment in a given context. If we subscribe to the bundle analogy, definitions of empowerment should not therefore be regarded as merely describing a way of informing social action under a common approach (like in the '*continuum* view'). Quite the contrary, the bundle analogy takes definitions as making claims on the agents involved, on their mutual obligations, and on the *values* fostering the empowerment goals of 'control over life and health', or 'responsibility for health' (Korsgaard 1996). This means that analysing different bundles (i.e. concepts) of empowerment demands identifying the sticks (i.e. values) that constitute their substantive underpinnings. For instance, let us consider the following definition by Tengland (2008, p.93):

> We achieve empowerment […] when a person (or group) A acts towards (in relation to) another person (or group) B in order to support B (by creating the opportunity and environment, and giving 'expertise' support) in gaining better control over (some of) the determinants (those relevant for the situation or profession) of her (quality of) life through (necessarily) an increase in B's knowledge (self-knowledge, consciousness raising, skills

> development, or competence), or health (e.g., autonomy, self-confidence, selfefficacy, or self-esteem) or freedom (positive and negative), and this acting of A towards B involves minimizing A's own 'power' (or influence) over B with regard to goal/problem formulation, decision-making and acting, and B seizes (at least) some control over this situation or process (goal/problem formulation, decision-making and acting).

This definition illuminates clearly the values behind *this* concept of empowerment, and consequently determines also the normative exercises that are compatible with it. What we *owe* to an empowered individual, in Tengland's interpretation, is revealed in the number of entitlements, values and actions instrumental to the achievement of her empowerment. These may include providing her with genuine opportunities, or knowledge, or enhanced capacity for self-determination, which are compelled to produce a better mastery over determinants of quality of life, and consequently of health (Tengland 2008). Returning to the analogy of the bundle, this means that sticks in Tengland's empowerment bundle could, for example, be the entitlement to be respected and supported as an autonomous person in the case of personal empowerment; or to have the opportunities required to exert control over the environment that influences one's actions and health in the context of a community intervention. It is not necessary for each and every of these *sticks* to part of the *bundle* for empowerment to obtain.

Things stand differently if we look at the bundle of values on the basis of empowerment in the "new wave" discussed above. By paraphrasing Tengland's account, a tentative definition of the concept in EBRs and PM could in fact go as follows:

> We achieve empowerment when a person (or group) A acts towards (in relation to) another person (or group) B in order to support B (by creating the opportunity and environment, and giving 'expertise' leadership) in acquiring responsibility for her health (i.e. solving their health problems in concordance with treatment programmes, identifying strategies for prevention, treatment and management of disease), and in participating to the governance of healthcare (providing feedback on the quality of services received, and contributing to public decision-

> making about the system) through (necessarily) an increase in B's access to relevant knowledge with regard to her health.

This definition of empowerment summarizes the different approaches to the concept identified above within the new wave of EBRs. First, it reiterates the idea that the commitment to 'control' has currently been replaced by an emphasis upon 'responsibility' for health, which is articulated as accountability for enacting relevant knowledge to solve a given health problem (Great Britain 2008, 38) and to identify personalised strategies for prevention, treatment and management of disease (European Science Foundation 2012, European Commission 2013). Second, it also captures the idea that empowerment means, within this context, enhancing citizens' responsibility to partake to the governance of the healthcare system, i.e. it demands citizens to act as consumers with regard to the services they require and to provide feedback on the quality of care received (Great Britain 2004a). Third, this definition highlights also the new role designed for professionals by the new wave of EBRs. It refers to the idea, encountered above (Great Britain 2008, 2010a), that the shift towards empowerment of citizen patients demands leadership on the side of professional to fruitfully guide the lay public in seizing responsibility for their behaviours.

It will be already clear to the reader at this stage of the present analysis, how different are the *sticks* in the two empowerment-*bundles* hereby described, and consequently how it is likely that they demand a different ethical evaluation. Identifying the sticks that compose a particular empowerment bundle has therefore the merit of distinguishing among the entitlements traded off when acting on the basis of a given concept of empowerment, as well as illuminating the potential conflicts between resulting actions and obligations on the side of all the actors they involve. Each of these notions of empowerment prioritizes some individual health-related beings and doings, and focuses on the opportunities that are deemed relevant to realize those beings and doings (such as the genuine opportunities to increase health literacy, or the opportunity to have access to medically relevant information). And yet, trading off all of these values may not be an easy task. This point leads us to another possible aim of this section of the thesis: clarifying what kind of ethical controversies can be generated by the different substantive and normative elements of empowerment in the new wave of EBRs.

Three substantive domains of controversy in EBRs

So far, I have been purposely using concepts such as 'health', 'responsibility', or 'control' without particular qualifiers. This finds its justification in the descriptive purposes of the analysis above, aiming at an extended historical exposition of how developments in the empowerment discourse have operated a thorough reconfiguration of the normative foundations of the political, social and technical imaginary to which the approach is connected. However, it is also worth pointing out that the conceptual disagreement regarding the theoretical underpinnings of empowerment is likely to generate major ethical tensions in the implementation of the political vision of the new wave of EBRs. Most of the critics of these regulatory documents agree in fact that the shift towards individualized and participatory medicine envisioned by these EBRs will come at some moral cost (Salmon and Hall 2004, Veitch 2010, Juengst et al. 2012, Sandroff 2012). For this reason, this final section of the present chapter formulates some potential unwanted consequences of the approach to be normatively addressed in the remaining of Part 1. In particular, the new wave of EBRs can be found liable of three main ethical concerns.

Empowerment and the paternalism paradox

Empowering citizens' health is supposedly a useful strategy to renegotiate the relationship between medical experts and the public, which overcomes the so-called 'compliance model' of healthcare delivery (Swift 1984, Feste and Anderson 1995). In contrast to the latter – which regards the medical encounter as a process that both "persuades and prepares patients to carry out recommendations made by health professionals" (Feste and Anderson 1995, p.140) – the major emphasis of empowerment is on having the knowledge, self-awareness and skills (Rappaport 1987, Wallerstein and Bernstein 1988), as well as the opportunities (Tengland 2008), necessary to exercise control over quality-of-life-related health. Because of this view, empowerment is widely considered to avoid the paternalistic criticisms of the compliance model. Recent developments of the approach in the "new wave" of EBRs support however a rather different view of the relationship between professionals and patient citizens to be promoted by empowering processes. As showed above, the focus of some EBRs falls heavily on empowering *leadership* on the side of healthcare personnel to ensure the quality of outcomes of the care they deliver (Great Britain 2008, 2010a). Starting from this recognition, many critics of empowerment have questioned its declared anti-paternalistic virtues by pointing to an alleged contradiction within this discourse. Experts and policy-makers, they argue, do not use empowerment as an emancipatory ideology and discourse, which aims at changing the power structures in healthcare (Marmot et al. 2010). Rather, they employ it as rhetoric to conceal their continuing exertions of power-over their clients (Buchanan 2000, Salmon 2004, Cribb 2005, Juengst et al. 2012).

In this respect, they conclude, empowerment is *no less* paternalistic than the so-called 'compliance model', thus creating an ethical tension in the approach that can be characterised as a *paradox*. On the one hand, EBRs put a strong emphasis on responsibility and control as a renegotiation of power relationships between professionals and healthcare clients. Their declared intent is that of moving away from paternalistic professionalism and nannying state (Great Britain 2010e) towards a role of patients as equal decision-makers and experts in healthcare (Fox et al. 2005). On the other, the very idea of sharing the powers of doctors with clients is professionally centred, and demands leadership on the side of experts (Great Britain 2008, 2010e). By doing so, EBRs may reinforce the idea that the professional – even when committed to client's participation in the decision-making process – is "in the driving seat" (Cribb, 2005, p.45). The danger entailed in the anti-paternalistic language of EBRs is therefore that of masking a persistence of paternalistic values and power relations with the enfranchising rhetoric of patient-centeredness. How to solve this *paternalism paradox* in EBRs?

Empowerment, responsibility for health and the charge of healthism

This second critique exposes the risk, allegedly entailed in EBRs, to produce obligations on the side of citizens to conform to social expectations and interests regarding their health

(Cribb 2005, Holland 2007, Veitch 2010). As showed above, some of these documents put in fact a strong emphasis on ameliorating the general health of the population through the empowerment of citizens' responsibilities (Great Britain 2010a, 2010e). Diffusing responsibility for health within EBRs, builds therefore upon a specific consideration of the social good of health (Cribb 2005). Namely, EBRs conceive health as a common good whose pursuit requires the contribution of all members of society (Holland 2007). In doing so, they appear to assert not only the need for an approach to healthcare oriented by the preferences of the population. Rather, they instate also a different kind of responsibility, on the side of each of us, for supporting the system's efficiency and sustainability, through healthy behaviours. One obvious problem of empowerment approaches conceived as such is that they attempt at pursuing two radically different aims, which can hardly be reconciled (Holland 2007). On the one hand, EBRs aim at enhancing opportunities for self-determination of individual citizens with regard to health-related decision-making. They put an emphasis on patients and individuals assuming responsibility for selecting services, or managing their own conditions (Great Britain 2004a, European Science Foundation 2012). On the other, they seek to establish high quality levels of care for the population, and better health standards within the system (Great Britain 2008, 2010a, European Commission 2013).

In this respect, EBRs could be seen as a political effort devoted to conform individuals to the "healthy" standards in the minds of those in power (Holland 2007, Veitch 2010). Roughly put, according to this interpretation, their objective would be that of empowering individuals to freely choose healthier behaviours that are established by the healthcare system. This critique shows therefore that attention should be paid to the value assigned to health in EBRs, and calls for an understanding of health-related goods within their vision. If EBRs commit themselves to foster a culture of healthism (Minkler 1999, Greenhalgh 2004), a tension emerges between the aims of empowerment and its application to health. Placing a strong emphasis on the enhancement of responsibility can indeed being empowering for citizens, by enabling them to direct the management of their own health and the healthcare system. Yet, if health is presented as a standard to which all members of a community are *empowered* to conform, the system's rationale appears to switch from 'citizens make a choice' to 'ensuring that specific kinds of choices are made' (Veitch 2010). How then should we conceive health in EBRs, so as to avoid this potentially disquieting implication of their vision?

Empowerment, and the pitfalls of shifting responsibility for health

Finally, another ethical concern may be fostered by EBRs' emphasis on responsibility for health. Many of these policy documents recommend in fact citizens to be responsible for their health and with respect to their use of healthcare services and resources. Such shift in responsibility for health is presented as a core tenet of the broader *empowering* intent of putting individuals "at the heart" (Great Britain 2004a, 2004b, 2010a, 2010e) of the healthcare system, and raises questions about the interpretation of responsibility that are of utmost importance for the ethical appraisal of EBRs. Different interpretations of responsibility for health allow in fact invoking different ethical or critical evaluations of EBRs.

This critical uptake of EBRs highlights the negative aspects of 'responsibilization' for health by stressing the potential unwanted consequences of assuming that people can be held morally responsible for their health (Minkler 1999, Wilkinson 1999, Buyx and Prainsack 2012, Brown 2013). From this perspective, the main problem with EBRs is not that they invoke responsibility for the promotion of a particular standard for health across the population (see above). Rather, it is the assumption that agents are *sufficiently free so as to be in charge of their health-related choices*. An uncritical attribution of responsibility for health that does not take into account this issue, critics argue, simply ignores the psychological mechanisms underlying the social distribution of health, and may introduce or accentuate health inequalities in the general population. Extensive evidence (Marmot and Wilkinson 2005, World Health Organization 2013) has been in fact produced regarding the gradient between health and socio-economic status. Roughly put, this evidence shows that the lower the socio-economic status of an individual is, the higher the likelihood that she will experience poorer health outcomes. This is mainly due to differences in power, skills and resources within a given population, and implies that shifting responsibility from the system onto the hands of patients could *disempower* rather than empower certain groups of our society. Although it appears to fall within one's powers to refrain from risky behaviours, or – as I argued – to pursue one's own standard of health, it is also important to keep in mind that unhealthy behaviours are less about personal control than EBRs assume. How to make sure that EBRs do not unfairly inflate citizens' responsibility for their health?

Part 1 of the thesis is dedicated to addressing these three categories of issues. The general argument that I will propose is that empowerment, as it is presented in EBRs, can be considered a defensible and feasible feature of future healthcare systems only if its understanding is capable of addressing and resolving the aforementioned ethical concerns. Otherwise stated, I maintain that tackling the ethical issues potentially arising from EBRs must be an explicit objective for advocates of empowerment – along with the development of strategies for its achievement and implementation – if the approach has to be considered not only for its "ideological soundness" (Tones and Green 2004, p.39), but also for its ethical sustainability. In doing so, Part 1 engages in a normative analysis of the foundations of empowerment, highlighting the substantive elements and values that should be at the basis of this approach.

Conclusions

The analysis presented in this chapter shows that the "new wave" of empowerment thinking in healthcare policy-making operates a thorough reconfiguration of the substantive and normative tenets originally attached to the concept. To this purpose, I presented a historical reconstruction of the different policy documents that, whilst revisiting the primary *raison d'être* of empowerment approaches to the governance of healthcare, appear to edify anew the substantive and normative foundations of the approach. In light of what I showed above, the new wave of EBRs is not to be merely understood as reiterating the benefits of disempowering healthcare institutions and professionals for the empowerment of citizens and patients. Rather, the new wave of EBRs should best be regarded as creating a new sociotechnical imaginary (Jasanoff 2009, Jasanoff and Kim 2013) about the political modalities of organizing healthcare and redistributing the onus of health and healthcare polity across society. Among the effects that this vision of healthcare is likely to foster, I argued, it is worth emphasizing how latest EBRs reconfigure the manner in which *patient citizens* should come to think of managing their health and illness in the terms of a proactive exercise of responsibility.

Furthermore, this chapter highlighted also how some disquieting implications are potentially yielded by the political endeavour of the new wave of EBRs, thus supporting the need of a normative appraisal of empowerment within this context. The main question that emerges from the present analysis is thus whether the empowerment approach has currently lost all of "its power" (Woodall et al. 2012), and still remains an ethically "sound and popular discourse" in healthcare policy-making (Veitch 2010, 314). Under the aegis of the new interpretation of empowerment presented above, igniting citizens' power-to control their own health (often framed in terms of responsibility rather than control) assumes, as we have seen, very different moral contours from the ones it had in the original formulation of the approach (Salmon and Hall 2004, Veitch 2010, Colombo et al. 2012). How to ensure therefore that this future scenario is an ethically desirable one?

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Chapter 2. Empowerment, compliance and the paternalism *paradox*

Introduction

As we have seen in Chapter 1, critics argue that the *anti-paternalistic* rhetoric of control and choice at the basis of empowerment in political discourse on healthcare reforms actually conceals a continuing exercise of power over healthcare clients that can be qualified as an instance of paternalism. To this view, one of the main outcomes of EBRs is that professionals can continue to exert power-over their clients (like they did under the so-called 'compliance model'), whilst at the same time using the emancipatory ideology and discourse of empowerment (Buchanan 2000, Salmon 2004, Juengst et al. 2012).

I call this tension, in the debate on empowerment, the 'paternalism paradox'. In order to address the critique entailed by the paradox, this chapter explores the relationship between paternalism and the empowerment approach. In particular, I single out what kinds paternalistic acts (if any) can be part of empowerment, and discuss the normative issues concerning their legitimacy. Accordingly, the chapter proceeds as follows: 1) I provide a working definition of paternalism for the purpose of identifying the paternalistic features of both the compliance model and the empowerment approach; 2) I take a hard look at the compliance model of healthcare delivery and I provide an answer to the question 'what is paternalistic in the compliance model?'; 3) I explore the reasons behind what I call the 'paternalism paradox' by assessing how (some accounts of) empowerment fall under the proposed working definition of paternalism; 4) siding with the critique entailed by the 'paradox' I then provide a normative analysis of the paternalistic features identifiable in (some accounts of) empowerment, and investigate whether they mimic the difficulties attributed to the compliance model; 5) I scrutinize whether paternalistic features are necessarily encompassed by different accounts of empowerment.

What I will conclude is that, all things considered, the 'paternalism paradox' applies only to some understandings of empowerment. Yet, the 'paradox' raises a relevant question regarding the *substantive* underpinnings of empowerment. It shows us that, in some of its declensions, empowerment fails to fully live up to the promise of being a *tout court* anti-paternalistic strategy for health promotion. In order to tackle this difficulty, I then present an understanding of empowerment that is free from paternalistic features, and hence capable to account for the promise of the anti-paternalistic revolution ascribed to EBRs.

A working definition of paternalism

In order to fulfil the aims of this paper, I need to identify a definition of 'paternalism' that can function as a benchmark for the identification of the paternalistic features in the compliance model and the empowerment approach. For this reason, this section explores some adequacy criteria (Gerring 2001, Tengland 2008) for the identification of a definition of paternalism both generally plausible and useful to the present analysis.

A first reasonable criterion to start from, in choosing a definition, is the so-called *language* criterion. Such criterion points to the advantages of developing formulations of a concept grasping its meaning and use in common language. In the case of paternalism, this means that the definition provided should capture shared uses of what counts as a paternalistic act. By incorporating social and psychological practices of a certain (i.e. the English-speaking) language community into the definition of a word, the *language* criterion has the advantage of minimizing conceptual confusion[7]. However, the *language* criterion needs to be tempered in the light of what shall be called the *descriptiveness* criterion.

The word 'paternalism' has in fact come to convey strong negative connotations in both ordinary and academic language. The value assigned to individual autonomy supports the widespread intuition that paternalistic behaviours, though not problematic in the exercise of

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[7] I am well aware that capturing the distinctive use of the term 'paternalism' in everyday language would demand a sociological appraisal of the gendered implications that the term has (Christensen and Hewitt-Taylor 2006). This represents an alternative line of reasoning for dismissing the legitimacy of paternalistic attitudes in the doctor-patient relationship, which I do not explore further in the thesis. However, my attempt to take up Kultgen's (1995) *parental analogy* in defining the term intends to make the reasons for defining paternalism oblivious as to their problematic gender biases. I only stick to the term 'paternalism' for the sake of consistency with the rich philosophical literature to which this analysis is meant to contribute.

parental authority and oversight, are morally suspicious when directed to competent adults. What seems to foster such recognition is the idea that adults are, in general, competent enough to make autonomous decisions and thus should not be equated to children (Sjöstrand et al. 2013). Yet, that does not mean that the concept should be best defined in evaluative terms. Defining paternalism in non-evaluative terms allows better distinguishing between acts of justified and unjustified paternalism, both when dealing with children or adults. The reasons for approving or condemning a certain act of paternalism are in fact independent from the ones that define the act paternalistic. For the purpose of this chapter, I will therefore make use of a descriptive definition of paternalism, which will be in turn used to normatively evaluate the legitimacy of a paternalistic act. Such descriptive definition of paternalism should help discuss and better determine its potential normative issues. The particular ethical analysis of paternalism presented here is not in fact intended to exclude different normative views about whether a certain paternalistic act is justifiable (or not).

Thirdly, the definition should preferably be formulated as a *conceptual theory* grasping the common characteristics of a class of entities deserving of being called with the same name. In other words, a useful definition should clearly provide the conditions that make a certain act paternalistic. The search for a conceptual theory of paternalism calls however for an additional – fourth – criterion to be employed in choosing its definition. As argued by Tengland (2008), it may be worth emphasize the *uniqueness* of the concept of 'paternalism' in relation to other germane concepts, such as simple beneficence or gift giving. Finally, we have the *analytic utility* criterion requiring us to elaborate a definition that can be beneficial to a particular analytic (or theoretical) context. This means, in the case of the present discussion of paternalism, that the definition employed should eventually facilitate the normative analysis of the compliance model and the empowerment approach.

Striking the balance between all of these criteria is no easy task. Some of them may conflict with one another – e.g. evaluative uses in ordinary language of the word paternalism make these definitions incompatible with the *descriptiveness* criterion. Some others may instead need to be tempered in order to be compatible with other criteria – e.g. uses in ordinary language of the word paternalism lack the level of abstraction required by the *theory* criterion. Thus, what I will attempt here is finding a compromise between all the criteria suggested, which will result in a working definition of paternalism. Such definition will be then useful to a critical scrutiny of the compliance model and empowerment.

Let us consider first the following definition famously proposed by Dworkin (1972). According to the author, paternalism is: "the interference with another's liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests or values of the person being coerced" (Dworkin 1972, p.65). This definition sets two fundamental criteria for an action to be considered paternalistic: a) the element of *benevolence*: the act should be taken for the welfare, good, happiness, needs, interests or values of the paternalised; b) the violation of liberty: it has to *actually* interfere with the liberty of action of the paternalised. Otherwise stated, a key aspect of Dworkin's definition is that actions are paternalistic, only if (i) they are successful in being liberty-limiting and (ii) are expected to yield a benefit (in terms of welfare, good, happiness, needs, interests or values) for the recipient. This account of paternalism has been thoroughly revised across the years (Dworkin 1995, 2010). Currently[8], Dworkin's definition of paternalism extends the above-mentioned condition b) to all the "usurpations of decision-making" (Dworkin 1995, p.220), thus holding that interferences with liberty and/or autonomy (together with the element of benevolence) are required for an action to qualify as paternalistic. According to this latter definition, paternalism obtains when people are prevented – for beneficent reasons – from doing something they have decided, or by "interfering with the way in which they arrive at their decisions" (Dworkin 1995, p.220).

Dworkin's account of paternalism appears to fare quite well with respect to the adequacy criteria set above. First, it provides us with a clear understanding of which

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[8] The latest development in Dworkin's scholarship on the concept of paternalism can be found in Dworkin 2013. Rather than proposing his own theorization of the concept, here the author discusses the long-standing controversy as to how paternalism should best be defined. I do not discuss this piece of Dworkin's work in this chapter, due to the relatively little contribution it may bring to its purposes. However, my analysis of paternalism is thoroughly indebted to the recognition of the author that, although conceptual analysis of paternalism is mostly devoted to the resolution of substantive conflicts, definitions are not, strictly speaking, required for normative arguments (Dworkin 2013, 33). As it may be clear to the reader, I take up this suggestion by adopting a *descriptiveness* criterion in my analysis of paternalism.

conditions should be met in order for an action to be paternalistic (*theory* criterion). Paternalistic actions are qualified as interferences with individual decision-making, motivated by an expected improvement of individual welfare, good, happiness, needs, interests or values. Second, it refrains from specifying whether paternalism is an inherently good/bad practice, thus relegating arguments for its condemnation (or justification) to a different and independent layer of analysis (*descriptiveness* criterion). Third, the concept of paternalism thus understood is distinct from other practices motivated by beneficent motives. Coercive and manipulative practices, for the sake of the recipient's benefit, are the *unique* class of actions that satisfy the criteria set by the definition. Finally, this definition appears to be *analytically useful* to the purpose of its potential ethical justification. It clearly identifies the moral *loci* (i.e. the element of benevolence, as well as the interference with the recipient's liberty and/or autonomy) of concern for its normative analysis.

Nevertheless, it is worth noting how Dworkin's definition is not free from defects. As argued by Kultgen (1995), philosophical understandings of paternalism are defective because they are narrower than its popular uses. According to Kultgen, philosophers fail to capture what is meant by paternalism in ordinary language (*language* criterion), and especially within the practice of healthcare (Buchanan 1978, p.371). Under this interpretation, a key aspect for the definition of paternalism lies in the *parental analogy* defining the term in its common use. Taking up such *analogy* points to the similitudes between paternalistic relationships and parents caring for a child (Kultgen 1995, p.47). Rather than emphasizing the mere interference with the liberty/autonomy of an agent, the parental analogy suggests that a relevant component of what makes an act paternalistic is the *attitude* that an agent (e.g. the state) might take towards another agent (e.g. citizens). There is no need for paternalistic actions to interfere with the autonomy, or liberty of the recipient. The paternalised (e.g. a child) "may have no capacity for decision-making for the paternalist to usurp" (Clarke 2002, p.87). It is rather the attitude of the paternalist – recapitulating those of caring parents – what defines paternalism, together with the commitment to the good of the paternalised.

What seems problematic in light of this consideration is the second condition identified by Dworkin's definitions. Claiming that paternalism occurs only when actions are effective in limiting liberty and/or autonomy, and for the recipient's good, does not account for the idea – dictated by the *language* criterion – that *attitudes* are what qualify paternalistic behaviours of parents in ordinary language. Taking up the parental analogy, therefore, exposes actions as paternalistic not only if an actual interference with individual decision-making occurs together with the promotion of the recipient's good. Rather, paternalism should describe, under this interpretation, an influence over the paternalised, which is not exhausted by interferences with decision-making. A form of control and authority exercised *par excellence* on children, for the sake of promoting the recipient's good "regardless of [her] short-term pleasures, desires, and wishes" (Kultgen 1995, p.50).

In light of this consideration, what I need is therefore a revised definition that tempers Dworkin's second condition with the idea that not all paternalistic actions must limit decision-making, for the sake of bringing about the good of the recipient. In particular, this condition defining paternalism should take into account the intuition that what makes an act paternalistic depends from the attitude deployed in promoting the good of the recipient. To better elucidate this point let us consider the following case from Hershey (1985):

> Suppose, for example, that the aunt of a young student wants to help her niece by transferring a certain amount of money to her account on a regular basis. She does so because she is aware that her niece has serious troubles with numbers leading her to write wrong checks. This happens to such a degree that the young student's resources are never sufficient to provide her adequate means of support. Furthermore, the father of the student (the aunt's brother) is outraged when he finds out that his daughter is draining some of the resources he provides her with. For this reason, he would harshly castigate his daughter. The aunt, who works in a bank, knows about these conflicts between her niece and her brother, and therefore she would give her niece this money even if she did not desire it. The fact that she has access to the bank account of the niece allows her to deposit this money in a way that neither her brother nor her

> niece would ever find out about it. Her main concern is that of avoiding contrasts between the two, and making sure that her niece has all that she needs to complete her studies.

The aunt in Hershey's (1985) example does not appear to interfere with her niece's liberty of action. It could be rather argued that, by providing her with the material means she needs to complete her studies, the aunt is actually enhancing the liberty (i.e. freedom of opportunity) of her niece (Sen 1985). Neither does she appear to violate the autonomy of the niece, if we conceive autonomy as the reflective endorsement of one's values, desires and commitments (Frankfurt 1971). The niece had no stance (she does not know) about the aunt making an extra deposit in her account, thus the aunt did not interfere with the wishes, desires, choices, or actions of the niece. Nevertheless, Hershey contends that there are good reasons to conclude that the aunt in the example is acting paternalistically towards her niece. What is it that makes her act paternalistic?

According to Hershey (1985), the element prompting the recognition of the aunt's behaviour as paternalistic lies in the fact that the money transfer is performed *regardless* of her niece's consent or dissent. Otherwise stated, the aunt intends to benefit her niece and in doing so she considers her potential preferences (which could be manifested through consent or dissent) as "irrelevant or motivationally impotent" (Hershey 1985, p.178). Should the niece consent or dissent to the money transfer does not make a difference to the aunt. This is not meant to exclude that paternalistic actions may involve violations of liberty and/or autonomy. The *attitude* of the aunt may (or may not) violate the niece's autonomy and/or liberty. If the niece had a stance against the money transfer, the aunt's behaviour would in fact qualify as a violation of the niece autonomy. However, for the recognition of the act as paternalistic this is not what matters, according to the view I am endorsing here (Hershey 1985).

To sum up, the *attitude* of discounting the (unknown) preferences, wishes, choices, or actions of her niece is what makes her act paternalistic according to Hershey (1985). Following this suggestion, I maintain that the lack of consideration for the recipient's consent or dissent can be regarded as a better second condition for identifying a paternalistic action. In particular, this new condition seems to account for the intuition described above (complying with the *language* criterion) that paternalistic conduct does not necessarily entail explicitly interfering with the liberty and/or autonomy of the subject. It is rather a form of control and authority exerted on the recipient of the act.

Let us then consider a definition of paternalism taking on board all of the above considerations: an action is paternalistic if and only if it is (i) intended to promote the *good* of the recipient in terms of individual welfare, good, happiness, needs, interests or values, and (ii) the *consent* or *dissent* of the recipient is not a relevant consideration for the initiator of the act. This definition adopts the first condition of Dworkin's account of paternalism and preserves some of its strengths. Similarly to his account it satisfies: (1) the *theory* criterion (it clearly states the common characteristics of the class of acts deserving of being called 'paternalism'); (2) the *descriptiveness* criterion (the normative evaluation of the practice is not entailed in the definition); (3) the *uniqueness* criterion (beneficent actions discounting the consent or dissent of the recipient are the unique class of actions that follow under the definition); (4) the *analytic utility* criterion (it brings into focus the potential *loci* of ethical concern useful to its normative analysis – e.g. on which grounds can the paternalist beneficent motives justified to discount the consent or dissent of the recipient?). Furthermore, it also fares better with regard to the *language* criterion, by taking on board Hershey's suggestion that the consent or dissent of the recipient might be regarded as a relevant constituent of what makes an act paternalistic. Such condition captures the idea, present in the common use of the term, that paternalism entails an attitude towards exercising control and authority analogous to the behaviour of a father towards his children.

Differently from past influential analyses of this concept (e.g. Dworkin 1972, 1995, 2010), the definition I presented here does not confine paternalism to the sole performance of liberty and/or autonomy limiting acts, but rather to the invocation of specific reasons and motives (epitomized by the relevance assigned to attitudes) for certain actions (Grill 2007). Namely, paternalism comprises those actions moved by *beneficent* motives that entail the *attitude* of considering the consent or dissent of the recipient motivationally unimportant. In doing so, the account proposed here does not aim at providing a necessarily original account of paternalism, but only at taking into account the attempts at opening up philosophical understandings of paternalism to the range of shared and lay intuitions about what makes an act paternalistic.

What is paternalistic in the compliance model?

Given the identification of a definition of paternalism both plausible and suitable to the purposes of this chapter, I now move to investigate whether and why the compliance model falls under such a definition. The aim of this section is thus to test whether it is possible to identify paternalistic features in the compliance model, and to analyse whether this recognition could be a source of legitimate ethical concern.

As noted by Kyngäs and colleagues (2000), the concept of 'compliance' refers to the extent to which a patient's decision coincides with medical or health advice. This means that, with regard to its general definition, the concept does not explicitly encompass any commitment to paternalistic intervention. Yet, the notion of compliance is widely regarded as an ideology that emphasizes the professional power of healthcare providers (Anderson and Funnell 2005). Advocates of empowerment have always questioned the compliance model of healthcare delivery for its narrow focus on treatment adherence and health outcomes (Raymond 1984, Feste and Anderson 1995). This commitment to clinical endpoints, they argue, is likely to result in an attempt to persuade patients to accept predetermined healthcare goals, thus reducing their autonomy and freedom of choice. Other critics (Cribb and Entwistle 2011, Sandman and Munthe 2010) have instead investigated the ethical implications of such focus, concluding that this model is paternalistic. However, little explanation is provided as to which paternalistic features they identify in the compliance model. On what basis then is the compliance model presented as an instance of paternalism?

At this stage of my analysis, it is worth emphasizing how such recognition depends very much on the definition of paternalism we employ. The analysis of paternalism above shows us that controversies surrounding its philosophical understandings (Dworkin 2013) should make us cautious in concluding that the compliance model is a *paradigmatic* example of paternalistic care (Feste and Anderson 1995, p.140). I will not delve into the reasons behind different accounts of paternalism that would not recognise professional behaviour to be paternalistic if it aims at using expertise power to persuade patients into a clinical outcome[9]. What I will probe, instead, is whether the definition of paternalism I proposed allows us to recognise some paternalistic feature(s) in the compliance model. Let us consider the following situation:

> Jenny is a 38 y/o woman who has just married the person she believes is the love of her life. After a gynaecological check-up she is unfortunately diagnosed with cervical cancer. Her doctor, Yuri, decides to perform on her a lymphadenectomy. In addition to this, he suggests also adjuvant chemo-radiation, an additional therapy usually given after surgery in cases where there exists a statistical risk of relapse due to occult disease. Jenny has promptly consented to the lymphadenectomy, and now faces the choice of whether to accept the after-surgery treatment. If she accepts the procedure she will likely lose her fertility. Without undergoing chemo-radiation, instead, she still has the possibility of giving birth to a child through gestational surrogacy (i.e. having a child genetically related to her parents and not to the surrogate mother). Jenny knows the reality of her condition, but she strongly believes that having a child biologically kin to her and her newlywed is what best conforms to her values and desires. The doctor understands that Jenny has some difficulties in coping with the decision at stake. For this reason (and for the sake of her own good), he repeatedly uses his authority to persuade the patient to change her mind, by prospecting her that (i) adjuvant chemo-radiation could decrease the risk of relapse by 40-50%, and (ii) the chances of obtaining a successful pregnancy are less than 10%.

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[9] Dworkin's first definition (1972) is a good example of the difficulties, for the critics of the compliance model, arising from a narrow view of paternalism. While the first condition in Dworkin's definition (i.e. the commitment to the good of the paternalised) does not create much of a problem to the critics of the compliance model, difficulties arise when we claim actions to be paternalistic only if they succeed in being for the recipient's good. Though being committed to the therapeutic goals of care, the compliance model does not entail necessarily ignoring or infringing patient's liberty. Rather, patient's perspective is simply taken as not being on a par with the one of the professional. It may therefore well be that the professional in the compliance model does not succeed to coax the patient into her expectation. Was this the case, the exercise of persuasion entailed by the compliance model would not be deemed paternalistic in Dworkin's terms.

The fictional case of Jenny presents us with a situation exemplifying the compliance model. A patient is confronted by a professional for the purpose of making her comply with what is medically good for her. In particular, Jenny's case portraits a contrast between what the patient perceives as her own good, and what the doctor thinks instead could best benefit the patient. Jenny is competent enough to be considered capable of autonomous and rational decision-making. Her decision to refuse adjuvant chemo-radiation resorts to her deepest values and desires. Nevertheless, Yuri believes that the motives at the basis of her decision are fundamentally questionable. From his perspective, her conception of the good is simply inadequate because it would be different if she appraised the harms arising from her potential refusal of additional treatment. The upshot of this situation is that Yuri *repeatedly* attempts to persuade Jenny into making a therapeutic decision that would best conform with her medical interest. In doing this, he does not consider relevant whether she would reach her decision in full autonomy, or not.

Is this example of the compliance approach to medical decision-making an instance of paternalism? Recall the two conditions above: (i) the act has to be intended to promote the good of the recipient in terms of individual welfare, good, happiness, needs, interests or values; (ii) the consent or dissent of the recipient is not a relevant consideration for the initiator of the act. Both of these conditions obtain in the fictional case of Yuri and Jenny. First, Yuri takes action (i.e. an exercise of authoritative persuasion) in order to benefit Jenny. As a professional, he is committed to the principle of beneficence and tries to convince her to follow the best treatment plan available for her condition. He genuinely intends to promote the *good* of his patient, thus satisfying the first condition set for an act to be paternalistic. Second, Yuri performs his act of benevolence independently from Jenny's wishes, choices, or actions. He exerts his professional authority in order to convince Jenny about what biomedical research statistically suggests being in her interest. He does so in a way that Jenny's perspective does not make a difference in his decision to act. Although Yuri does not coerce Jenny in any way, he discounts her point of view. Differently from the doctor's perspective, her reasons are simply not considered in the decision-making process to which both partake.

This independence in Yuri's decision to act (i.e. exert authoritative persuasion) characterizes Jenny's perspective as motivationally impotent. Otherwise stated, Jenny's potential *dissent* to receive the adjuvant treatment, as well as to be persuaded onto complying with professional advice, are not a relevant consideration for Yuri's exercise of professional authority. This means that also the second condition for paternalism obtains in this situation. If we combine the two considerations above, it is thus possible to conclude that the case of Jenny and Yuri – capturing the characteristics of decision-making within the compliance model – is an act of paternalism.

To sum up, the fictional example of Jenny and Yuri allows a better qualification of the recognition that the so-called compliance model of healthcare delivery is indeed paternalistic. Roughly put, the compliance model can be deemed paternalistic because it systematically discounts the perspective of the patient for the sake of her own medical good. Furthermore, if my analysis of a working definition of paternalism holds, it is also safe to conclude that such recognition is concordant with a reasonably plausible understanding of paternalism. Detecting the paternalistic features of the compliance model, however, tells nothing about its ethical evaluation. The next step for the present analysis is, therefore, to understand whether the compliance model is a worrisome form of paternalism.

The answer to this question lies in a number of possible ethical considerations. First, the compliance model appears to endorse a narrow view of what medical *beneficence* entails. What is good for the patient is provided a meaning specific to medicine, which is identified by a professional on scientific grounds (Sandman et al. 2012). Although it is obvious that doctors are in general more knowledgeable as to the best medical option available to their patients, such conception of beneficence runs the risk of disregarding the short and long-term goals of the patient. By contrast, it could be argued that the example above shows no major violation of autonomy. It is in fact generally held, in medical ethics, that overriding patient perspective for the sake of improving decision-making competence is in the end beneficent to the patient (Beauchamp and Childress 2001). Yuri's actions aim at providing Jenny with more detailed information about the potential consequences of her choice, thus preserving and improving her long-term autonomy. According to this perspective, Yuri's action would not be ethically problematic because the positive value of making his patient's decisions more informed outweighs the negative value of imposing information onto Jenny.

However, a different evaluation of Yuri's behaviour can be also grounded on considerations of autonomy. This second line of reasoning would deem problematic, in Yuri's paternalistic behaviour, the fact that he considers legitimate to authoritatively (attempt to) coalesce Jenny into what is good for her from the medical point of view. This concern about the compliance model is, in other words, that it disfavours a full recognition of patient's perspective as the ultimate guidance for clinical decision-making (Cribb and Entwistle 2011). Jenny is not consulted as an equal participant to the medical decision-making process. Rather, her preferences are simply considered not authentic enough (because they are not scientifically informed) to be on a par with those of Yuri (Sjöstrand et al. 2013). To this view, it is the imbalance of power between the non-expert patient and the physician functioning as a "purveyor of expertise" (Tauber 2005, p.62), what makes ethically problematic the compliance model. It could be in fact argued that the notion of authentic autonomous agency encountered in the case of Jenny and Yuri is philosophically naïve. A substantive disagreement exists in fact in the philosophical literature about what counts as an authentic autonomous decision, and especially as to the role that cognitive, affective, valuational, and dispositional states play in the constitution of an authentic expression of the will (Oshana 2007). Regardless of this complexity, the compliance model conflates authenticity of patient's decisions with the capacity to govern one's own health accordingly to scientifically informed beliefs. By doing so, the compliance model conveys therefore the message that healthcare professionals know better than patients what is best for them *because of their scientific expertise*, thus legitimising potential exercises of arbitrary power in the doctor-patient relationship (Holm 1993, Sandman et al. 2012).

In conclusion, the example of Yuri and Jenny describes a situation where the clinical interest of a patient is presented independently from what the patient might perceive as her best interest in the light of her values and beliefs. The professional is (i) considered to know best what is good for the patient, and (ii) expected to authoritatively persuade the patient into what is good for her (from the professional point of view). Through the lens of the 'compliance model', we can conclude, collaboration between the doctor and the patient is thus understood in terms of an obligation (Evans 2007) to follow medical advice, grounded on considerations of beneficence. Such strong focus on health outcomes, however, can lead to neglect other important entitlements ascribable to patients in contemporary healthcare. The commitment to the respect of patient autonomy can hardly be reconciled with the idea that a poorly (or not) compliant patient ought to be regarded as unable to grasp what is good for her, and/or lacking the ability to authentically choose in their own best interest.

Empowerment and the 'paternalism paradox'

Evaluating the paternalistic features of the compliance model is pivotal to the forthcoming analysis of what I shall call the 'paternalism paradox'. In order for the paradox to hold water, it is necessary to single out whether some accounts of empowerment can give rise to actions comprised by the definition of paternalism defended above. As we will see in the remaining of this section, proponents of the 'paradox' are concerned with the potential drawbacks of empowerment in the context of contemporary personalised medicine. In a nutshell, they argue that it is possible to identify *paradoxical* paternalistic outcomes to specific accounts of the non-paternalistic discourse of empowerment.

This critique takes off from the widespread appeal to personalized genomic medicine, which has gained enormous popularity in the last decade (Juengst et al. 2012[10]). In particular, the authors take a hard look at the rising vision of medicine equating empowerment with (i) enhanced participation to decision-making processes, and (ii) higher availability of health-related information (e.g. genomic information). The intent of their analysis is to highlight how the appeal to empowerment is not as uncontroversial as it might appear under the aegis of

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[10] As referenced accordingly by Juengst et al. (2012), the argument against paternalistic outcomes of personalised genomic medicine builds upon a paper by Prainsack and colleagues (2008). I use the work of Juengst et al. (2012) for the purpose of my analysis because the original paper revolves around the potential unwanted consequences of pushing individual responsibility for health in direct-to-consumer genetic testing, rather than on the analysis of its paternalistic features.

personalized medicine. Building upon the market rhetoric surrounding empowerment within genomics, they show that this approach has a fundamental "vice" (Juengst et al. 2012, p.36). Namely, it relocates responsibility for health from traditional healthcare structures onto the hands of patients. The language of empowerment is often associated with rhetoric of liberation from the oppression of paternalistic expertise. However, the enthusiasm surrounding such a paradigm-shift runs the risk of obscuring its potentially paternalistic drawbacks.

In order to better illustrate this point, let us consider a different version of the thought experiment we analysed in the case of the compliance model:

> Jenny is a 38 y/o woman who has just married the person she believes is the love of her life. After a gynaecological check-up she is unfortunately diagnosed with cervical cancer. Her doctor, Yuri, decides to perform on her a lymphadenectomy. In addition to this, he suggests also adjuvant chemo-radiation, an additional therapy usually given after surgery in cases where there exists a statistical risk of relapse due to occult disease. Jenny has promptly consented to the lymphadenectomy, and now faces the choice of whether to accept the after-surgery treatment. If she accepts the procedure she will likely lose her fertility. Without undergoing chemo-radiation, instead, she still has the possibility of giving birth to a child through gestational surrogacy (i.e. having a child genetically related to her parents and not to the surrogate mother). Jenny knows the reality of her condition. She has been *empowered* with all the relevant information on her health status, and asked to decide about the after-surgery treatment. However, she is uncertain about whether having a child biologically kin to her and her newlywed should prevail over the possibility of reducing the risk of relapse. The doctor understands that Jenny has some difficulties in coping with the decision at stake. Among the possible ways to react to this situation (and for the sake of her own good), he decides to repeatedly use his authority to persuade the patient to accept his advice, by prospecting her that (i) adjuvant chemo-radiation could decrease the risk of relapse by 40-50%, and (ii) the chances of obtaining a successful pregnancy are less than 10%.

This alternative version of Jenny's fictional case shows us that we should not assume that empowerment always "yields positive outcomes" (Juengst et al. 2012, p.36). In this situation, Yuri behaves in conformity to the account of empowerment presented by Juengst and colleagues (2012). He provides the patient with all the *information* available, and lets her the possibility to *decide* what is best for her. This is indeed what the notion of empowerment at stake here prescribes him to do. However, this shift in responsibility appears to be counterproductive for the patient. Jenny has some difficulties in taking up the responsibility of choosing between having a child with her newlywed, and consenting to the adjuvant therapy. By "styling participation as an expansion of patient control" (Juengst et al. 2012, p.38), such notion of empowerment burdens the patient with an obligation to exercise control over the healthcare process. This state of affairs puts some pressure on Jenny, which weakens her capacity to resist to Yuri's same *paternalistic* interference we encountered in the case of the compliance model. In other words, Juengst and colleagues (2012) point to the risk of patient empowerment collapsing into the ambiguous benefit of having more information at patient's disposal (e.g. genomic susceptibilities in their analysis), without the capacity of understanding, managing, and directing it in an autonomously chosen course of action.

This revised version of Yuri and Jenny's case highlights therefore the shortcomings of the view of empowerment, which is a major concern for the proponents of the 'paradox'. First, by reducing patient control to enhanced and informed participation, empowerment (understood as such) creates a "whole range of complementary obligations on the patient's part" (Juengst et al. 2012, p.38) that might run up against its own objectives. Jenny is given the burden of making an important decision regarding her life, without any consideration of the difficulties originating from her *empowered* role. An undesirable consequence of (this account of) empowerment might be, therefore, the creation of an undue pressure on the side of patients originating from their lack of capacity to direct genetic information in an autonomously chosen course of action. Second, the case of Jenny and Yuri shows that, "when falling into medicine's traditional domains of authority" (Juengst et al. 2012, p.39), the emphasis on empowerment *potentially* results in an increase of patient compliance with medical recommendation. Jenny lacks the ability to cope with the decision to accept or refuse adjuvant chemo-radiation. This state of affairs puts her in a weak position, which opens up the possibility of making her more exposed and vulnerable to Yuri's paternalistic interferences.

Juengst and colleagues (2012) point, in other words, to a legitimate concern regarding the theoretical underpinnings of a specific conception of empowerment. They subject to critical scrutiny the unintended consequences of the personalized medicine discourse. In brief, the paternalism paradox points to the fact that, regardless of the anti-paternalistic allure often ascribed to empowerment, some uses of the concept have actually the potential unwanted consequence of opening up possibilities for paternalistic interferences to be furthered in the doctor-patient relationship. In doing so, the critique of Juengst and colleagues (2012) hints at the possibility that paternalistic outcomes of empowerment may depend on how the concept is conceived, understood and implemented in practice.

Empowerment is *no less* paternalistic than the compliance model

In the previous section, I showed how the empowerment approach could result in the same paternalistic behaviours ascribable to the so-called compliance model. This means that critics are right in pointing out that empowerment, in some of its understandings, is no less paternalistic than the compliance model (Buchanan 2000, Holland 2007, Juengst et al. 2012). Differently from the compliance model, however, the empowerment approach analysed above entails paternalistic behaviours on the side of professionals only as a *possibility* (among others) resulting from the kind of relationship it instates. Due to the difficulties, on the side of Jenny, to cope with the devolution of responsibility for health entailed in this account of empowerment, Yuri can exercise on her the same kind of paternalistic interference he is *compelled* to in the previous scenario from the compliance model. This means that a fundamental difference exists between the compliance model and the empowerment approach, as it has been analysed so far. In the former, paternalistic behaviours of healthcare professionals are ingrained in the understanding of agency and obligations of a doctor towards a patient. The patient's view is deemed not to stand equal foot against the one of the doctor, who is consequently required (for the patient's own good) to authoritatively persuade the patient into medical advice regardless of her potential consent/dissent. Things stand differently however, if we take into account the fictional scenario epitomizing the empowerment approach in personalised genomic medicine. Here, the professional is required to step in the direction of a devolution of his power to the patient, by providing her with all the relevant information on her health status, and by asking her to take up the responsibility to decide about the after-surgery treatment. However, the difficulties encountered by the patient in coping with this burdensome task leave open the *possibility* for the doctor to exercise the very same kind of paternalistic interference he was compelled to by the compliance model.

In other words, the paternalism paradox stems here from a limitation of this account of empowerment, which is unable to keep up with its own anti-paternalistic promise. The accounts of empowerment liable to the paternalism paradox hint at the potential benefits arising from having at one's disposal more information and participating in decisions about health. However, what these understandings of empowerment fail to account for is that the success of this strategy is linked to individuals grasping the information and choosing to act upon it. This means that critics of empowerment are right in pointing out that medical information may be difficult for patients to manage and that, consequently, empowerment is likely to open up a space for authoritative persuasion in the process of delivering medical information to healthcare clients.

Similarly to the case of the compliance model, some ethical concerns can thus be recognised in the account of empowerment liable of the paternalism paradox. First, one could map this account onto the narrow view of medical beneficence ascribable to the compliance model. The understanding of empowerment at the basis of the paradox allows in fact for the imposition on patients of the same narrow focus on health outcomes, which has proved problematic for the compliance model. The space left for authoritative persuasion in empowerment could be subverted as a "device for increasing patient compliance with medical recommendation" (Juengst et al. 2012, p.39), in the light of the achievement of a clinical good. Second, a legitimate concern about (this account of) empowerment is that it fails to keep up with its commitment to the promotion of patient autonomy. Very much like in the case of the compliance model, empowerment appears to disfavour a full recognition of patient's perspective as the ultimate guidance for clinical decision-making. However, it does so in a different way from the compliance model. This account of empowerment makes appeal to the alleged importance of enhancing patient autonomy, but fails to keep up to its own promise.

In light of this recognition, I can now conclude that empowerment, through the prism of the *paradox*, appears to be a mixture of paternalism and authority that puts the individual in a weak position. The critique entailed in the 'paradox' reveals that some legitimate concerns exist as to whether processes of empowerment have the potential to yield their declared goals (Tengland 2007). In particular, it points to the necessity of improving our understanding of empowerment in a way that is compatible with the aims of the approach. Not only empowerment should aim at devolving decisional power to the patient, but also it should ensure that this process does not leave open a space for paternalistic interferences. Of course, this recognition holds only insofar as we want to fulfil the promise of empowerment to have a special "moral stand against medical paternalism" (Juengst et al. 2012, p.39). In the remaining of this chapter, I will present an understanding of empowerment, which avoids these unwanted outcomes. By doing so, my aim is to counter the objection entailed in the paternalism paradox, and clarify how processes of empowerment could consistently achieve empowering goals without being paternalistic.

How to prevent paternalistic outcomes of empowerment?

The recognition that paternalistic outcomes may be attributed to a given notion of empowerment questions the alleged ethical advantages of this approach *vis à vis* those of the compliance model (Swift 1984, Feste and Anderson 1995). In order to understand whether alternative accounts of empowerment can handle the problems arising from the paternalism paradox, it is necessary to delve into the diverse normative foundations at the basis of the concept. Defining the normative underpinnings of empowerment approaches is, however, no easy task because of the substantial philosophical disagreement on how to best describe the concept (Tengland 2007).

As we have seen in Chapter 1, the concept of empowerment was elaborated in disciplines such as liberatory pedagogy, social psychology, mental health and health promotion (Rappaport 1987, Wallerstein 1992, Rodwell 1996, Laverack and Labontè 2000). Within these contexts, empowerment has been associated with both of the distinct notions of *power* (Wartenberg 1990) highlighted above; that is, "power-to" and "power-over" (see *infra* Chapter 1). These two notions of power were originally meant to go hand in hand within the empowerment approach. A mere focus on individual enablement did not suffice, for its inventors, to produce the benefits ascribed to the approach. Quite the contrary, such outcome was deemed to be achievable only through intervention in the two domains of power. Roughly put, a gain of power at the *intrapersonal* level ought to necessarily be accompanied by changes at the *interpersonal* level, in order for empowerment to obtain (Minkler 1999).

Things stand differently, however, if we analyse latest developments in the empowerment literature, and what I called EBRs. In the last two decades, the focus of this approach has narrowed down to a specific interpretation of the idea of power-to, i.e. towards an emphasis on individual responsibility for health-related decision-making. As shown in Chapter 1, this is especially frequent in the policy-making literature, which has recently associated the concept with a neo-liberal and consumerist view of health-related agency (McGregor 2001, Veitch 2010).

If we scrutinize closely the notion of empowerment at the basis of the paternalism paradox (Buchanan 2000, Salmon 2004, Juengst et al. 2012) it is not difficult to recognize its resemblance with the latter family of empowerment approaches described here. Two assumptions appear in fact to underlie empowerment as questioned by its critics and the paternalism paradox: first, that providing individuals with relevant information and opportunities to exercise choice can be automatically considered an empowering step; second, that the achievement of empowering goals does not need to involve any influence over the "environmental and socio-organizational circumstances" (Owens and Cribb 2013, p.263) that affect clinical decision-making (e.g. the use of authoritative persuasion on the side of healthcare professionals). One question that could be asked at this point of our analysis is therefore whether accounts of empowerment of the first kind are actually able to prevent the paternalistic outcomes at the basis of the *paradox*. To this issue I now turn for the remaining of this section.

As showed above, traditional understandings of empowerment have to do not only with the goal of increasing ability and opportunities to exercise choice in medical decision-making, but also with the means that can be used within empowering processes to actually obtain them (Tengland 2007, 2008). From this perspective, empowerment is understood as letting the healthcare "client, group or community have as much control as possible over the change processes they are involved in" (Tengland 2012, p.143). However, what is also important – for this view – are the means that professionals are allowed to use for the achievement of the goals of empowerment (Tengland 2007). Some of them are considered to be compatible with its goals, some others are instead deemed to be in open contrast with them. Otherwise stated, traditional understandings of empowerment are based on a view of the professional-patient relationship, which is different from the one of its more recent versions (Juengst et al. 2012). Traditionally, empowerment theorists are concerned with the restrictive effect that medical expertise may have on individual ability to control medical decision-making. Many professional relations are considered, under this interpretation, as heralding "paternalistic outcomes", due to the "unbalance of 'power' (or influence)" between the professional and the client (Tengland 2008, p.91). The professional is often in the position of (i) structuring and guiding the clinical encounter with patients (Tengland 2008) due to her medical expertise, and consequently (ii) of exercising an influence over the patient that can be qualified – as we have seen above – as paternalistic. Yet, such kind of patient-professional interactions can hardly be reconciled with the goals of empowerment. Changing the power balance by limiting professional control is therefore, according to traditional accounts of empowerment, of pivotal importance to attain its goals. Empowerment as a process is in fact about letting the client actively participate in the decision-making process. This means that the professional should be primarily understood as an enabler or facilitator, who refrains from exercising a dominant role over the patient and supports the individual (or group) in addressing a problem through the use of empathic listening, non-judgemental attitudes, and genuine participation (Tengland 2012). No "persuading, rewarding, punishing, coercing or manipulating" (Tengland 2012, p.143) can be considered valuable means for the empowerment process.

Starting from this premise I can now attempt a final evaluation of our thought experiment involving Jenny and Yuri. What I will deploy in this version is the above-sketched understanding of empowerment as both a process and a goal, in order to test whether the requirement of a reduced professional control over the process is able to prevent its paternalistic outcomes:

> Jenny is a 38 y/o woman who has just married the person she believes is the love of her life. After a gynaecological check-up she is unfortunately diagnosed with cervical cancer. Her doctor, Yuri, decides to perform on her a lymphadenectomy. In addition to this, he suggests also adjuvant chemo-radiation, an additional therapy usually given after surgery in cases where there exists a statistical risk of relapse due to occult disease. Jenny has promptly consented to the lymphadenectomy, and now faces the choice of whether to accept the after-surgery treatment. If she accepts the procedure she will likely lose her fertility. Without undergoing chemo-radiation, instead, she still has the possibility of giving birth to a child through gestational surrogacy (i.e. having a child genetically related to her parents and not to the surrogate mother). Jenny knows the reality of her condition. She has been *empowered* with all the relevant information on her health status, and asked to decide about the after-surgery treatment. However, she is uncertain about whether having a child biologically kin to her and her newlywed should prevail over the possibility of reducing the risk of relapse. The doctor understands that Jenny has some difficulties in coping with the decision at stake. For this reason (and for the sake of her own good), he engages in a mutual exchange of views with Jenny as to the various options at her disposal. He provides her with his knowledge of the relevant facts about her condition: namely, that (i) adjuvant chemo-radiation could decrease

> the risk of relapse by 40-50%, and (ii) the chances of obtaining a successful pregnancy are less than 10%. Furthermore, he collaborates with the patient to facilitate her understanding of the problem and helps her identify a solution that best suits her desires and values, whatever it might be.

This different version of Jenny and Yuri's case displays the characteristics of empowerment we identified in its traditional understandings. This account shares in fact the goals of empowerment that we encountered in the analysis of the paternalism paradox (Juengst et al. 2012). Also in this case, Jenny is provided with all the *information* available regarding her condition, and is given a greater space for *deciding* about what is the best clinical option to her. However, differently from the previously examined version of empowerment, in this situation Yuri is bound also to the procedural requirement of reduced professional control over the empowerment intervention.

This obligation on the side of Yuri has an effect over his interaction with Jenny, which should now be examined as to its potential paternalistic features. Yuri's reaction to Jenny's difficulties of making the decision regarding adjuvant chemo-radiation is still animated by beneficent motives. He is committed, as a professional, to the principle of beneficence (Beauchamp and Childress 2001) and seeks an interaction with Jenny that genuinely intends to promote the *good* of his patient. In this respect, his action appears to satisfy the first condition I set for an act to be paternalistic. Yuri's motives are indeed aimed at improving his patient's welfare, good, happiness, needs, interests or values. Yet, his *attitude* towards Jenny appears to be rather different from the one encountered in the two previous versions of this case. The crucial difference here lies in the fact that Yuri supports Jenny in deciding what is best for her, rather than attempting to persuade her into the best medical option available. He does so because the procedural requirement of minimizing the use of his authority prescribes him to resort to specific means for the empowerment of his patient, which do no admit the use of authoritative persuasion (Tengland 2008, 2012). The notion of empowerment at the basis of this clinical encounter puts an obligation on the side of the doctor to fully respect and acknowledge the perspective of the patient. Such emphasis on respecting and furthering patient control is in sharp contrast with the attitude of considering motivationally impotent the consent or dissent of the recipient. Yuri cannot disregard the wishes, desires, choices, or actions of Jenny, if he has to act according to the remit of empowerment. This means that his action does not satisfy the second condition for paternalism identified above, and hence cannot be qualified as paternalistic interference.

What is worth emphasizing as to traditional accounts of empowerment is, in other words, that there exist means of promoting goals of empowerment that do not necessarily involve paternalism. By doing so, these means are also more congruent with the declared aims of the approach. Seeking an increase of patient ability in "the problem formulation, the decision process, and the actions undertaken" (Tengland 2012, p.146) may be implemented in practice through different degrees of influence over the patient. Some of these influences may be characterised as paternalistic, as shown in the previous sections of this work. It is important to note however that influences stand along a continuum, where at one end of the spectrum are coercion and deliberate uses of force, and at the other is letting the patient do what she prefers. In between we have influences like manipulation, persuasion, recommendation, encouragement, and provision of information (Tengland 2008) that leave the patient different degrees of control over the situation. If control over the healthcare process is to be considered a fundamental tenet of empowerment, what I can conclude from this analysis is therefore that the more the professional limits her paternalistic influence over the process, the more appropriate are the means deployed for achieving the goals of empowerment.

Conclusions

My main concern throughout this chapter has been to critically scrutinize what I characterized as the 'paternalism paradox' in the empowerment literature. According to this critique, there exists a sharp contrast between the declared anti-paternalistic aims of empowerment and its actual impact on healthcare relationships (Buchanan 2000, Salmon 2004, Juengst et al. 2012). Such paternalistic outcomes question the ethical advantages of the empowerment approach as opposed to the so-called compliance model – i.e. an approach to the healthcare relationships that emphasizes persuasion and compliance with medical recommendation (Swift 1984, Feste and Anderson 1995). In order to address this issue, I have first identified a definition of paternalism, which is not merely stipulative, but aims also at comprising some of the characteristics of this concept in the philosophical literature (Hershey 1985, Dworkin 1972, 1995, 2010). Such a definition enabled me to compare the characteristics of the compliance model and the empowerment approach through three different versions of a thought experiment involving a doctor (Yuri) and a patient (Jenny), exemplifying the moral reasoning behind the compliance model and two versions of the empowerment approach. In the analysis of this fictional cases I found that different approaches to the doctor-patient relationship may result in paternalistic interferences on the side of the professional, and that some forms of empowerment can arguably bring about paternalistic outcomes.

In order to mark the difference between the empowerment approach and the compliance model as to their potential paternalistic outcomes, one requirement emerged from my analysis. Namely, that the empowering means of the professionals should be made congruent with the empowerment goals – i.e. increased control for the client over the healthcare process (Tengland 2008). This means that my work acknowledges that there is something *paradoxical* (or at least problematic) about accounts of empowerment where the professionals are left in the position of exerting paternalistic influences over the client. However, this does not appear to be sufficient ground to question the merits of all versions of empowerment (Salmon 2004). With regard to this, I argued that paternalistic outcomes of empowerment could be possibly prevented by those accounts that consider professional reduction of power, control and influence over decision-making as one of their fundamental tenets.

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Chapter 3. Empowerment, responsibility and the charge of *healthism*

Introduction

This chapter addresses a second criticism of EBRs, which I call 'the charge of *healthism*'. Namely, their potential to produce obligations on the side of citizens to conform to social expectations and interests regarding their health (Cribb 2005, Holland 2007, Veitch 2010). As showed above (see *infra* Chapter 1), some of these policy documents put a strong emphasis on ameliorating the general health of the population through the declared intent of empowering citizens' responsibilities (Great Britain 2010a, 2010e). Such a diffusion of responsibility for health within EBRs builds upon a specific consideration of the social good of health (Cribb 2005). EBRs conceive health as a common good whose pursuit requires the contribution of all members of society (Holland 2007). In doing so, they appear to assert not only the need for an approach to healthcare oriented by the preferences of the population. Rather, they instate also a different kind of responsibility, on the side of each of us, for supporting the system's efficiency and sustainability through healthy behaviours. One obvious problem of empowerment approaches conceived as such is that they attempt at pursuing two radically different aims, which can hardly be reconciled (Holland 2007). On the one hand, EBRs supposedly aim at enhancing opportunities for self-determination of individual citizens with regard to health-related decision-making. They put an emphasis on patients and individuals assuming responsibility for selecting services, participating to public decision-making on the governance of the system, or managing their own conditions (Great Britain 2004a, European Science Foundation 2012). On the other hand, they also seek to establish high quality levels of care for the population, and better health standards within the system (Great Britain 2008, 2010a, European Commission 2013).

This two-sided commitment to responsibility within EBRs could be seen as an effort devoted to conform individuals to the "healthy" standards in the minds of those in power

(Holland 2007, Veitch 2010). According to this interpretation, EBRs represent the political enforcement of an obligation to comply with 'standards of health', or – to put it differently – to foster a culture of *healthism* (Minkler 1999). If this recognition holds, the objective of EBRs becomes the oxymoronic empowerment of individuals to freely choose healthier behaviours that are established by the healthcare system: a goal that raises a conflict between the supposed emancipatory aims of empowerment and its application to health. This charge of healthism shows, in other words, that attention should be paid to the value assigned to health in EBRs, and calls for an understanding of health-related goods within their political vision. If EBRs commit themselves to foster "healthist" expectations across society (Minkler 1999, Greenhalgh 2004), a tension emerges between other values at the basis of their political project. Placing a strong emphasis on the enhancement of responsibility is an empowering move for EBRs, because they explicitly resort – at least *prima facie* – to the value of providing citizens with the opportunity to direct the management of their own health and the healthcare system. Yet, if health is presented as a standard to which all members of a community are *empowered* to conform, the system's rationale appears to switch from 'citizens make a choice' to 'ensuring that specific kinds of choices are made' (Veitch 2010). The only choice that EBRs open up, if this healthist interpretation prevails, is whether or not to meet the expectations that the system places upon citizens' shoulders with regard to their health. Briefly put, their objective turns into the problematic goal of empowering individuals to "freely" choose healthier behaviours that are established by the healthcare system.

Recognising the charge of *healthism* calls for problematizing some of the substantive commitments entailed in EBRs. In particular, this critique demands tipping the balance between the value of efficiency-considerations for the system (Great Britain 2004, 2010a, 2010e), and the importance of the element of self-determination at the basis of responsibility claims on which EBRs put a strong emphasis (European Commission 2007). As we will see in the next chapter (see *infra* Chapter 4), many commentators have rightly displayed strong scepticism towards the moral legitimacy of holding citizens responsible not only the for taking up control over their health, but also for contributing to the sustainability of the healthcare system (Minkler 1999, Wilkinson 1999, Buyx and Prainsack 2012, Brown 2013). Yet, very little has been written on the importance of an evaluative appraisal of the concept of health for the legitimacy of the normative claims of responsibility for health (Cribb, 2005, Holland 2007). With regard to this, the present chapter shows that the concept of health is not morally neutral. Rather, the value we assign to health contributes to the desirability of the empowered role of healthcare clients envisaged by EBRs. If EBRs require placing an objectivist account of health (i.e. a standard of health determined a priori by means of biological and medical knowledge) at the centre of their new morality, and elevating it to the level of its primary value, their political discourse may actually restrain – rather than enhance – citizens' responsibilities for their health.

Understood as such, the charge of *healthism* calls for an understanding of how health-related goods ought to be conceived so as to avoid such an undesirable consequence. *Prima facie* this critique depends in fact upon the way we conceptualize the value of health. If EBRs commit themselves to a deterministic understanding of health, a tension emerges between the aims of empowerment and its application to EBRs. A healthcare system framed around such a conception of health entails the danger of allowing too little space for medicine to be sensitive or – as envisaged by EBRs – *tailored* to "individual and culturally specific constructs of health" (Cribb 2005, 24). By requiring citizens to conform to health-related expectations, EBRs would create a demand, rather than an opportunity to seize responsibility with regard to one's health. This means that a conception of health that is consonant with the aims of empowerment should be found, in EBRs, and that this theory should not conflict with the elements of self-determination and control that are distinctive of this approach. But, does such a conception of health exist?

In order to answer this question, this chapter will firstly turn to the analysis of a number of theories of health that currently dominate the philosophical debate. Different authors have in fact attempted at providing a "sufficiently circumscribed conception of health" (Cribb 2005, 22), but a controversy exists as to how health should be best conceptualized. Building upon the classification of theories of health proposed by Nordenfelt

(2012), I will discuss two types of theories of health (World Health Organization 1948, Boorse 1975, 1997). These theories are the objectivist 'biostatistical theory of health' (BTH) and the relativistic 'holistic theory of health' (HTH)[11]. Both accounts, I will argue, present limitations as to their conceptualization of health and health-related phenomena for their application to the context of EBRs. In particular, I will show that besides the motives at the basis of the charge of healthism in EBRs, we have compelling philosophical reasons to reject the BTH as a generally suitable theory of health. Moving on from this analysis, I will turn to the family of HTsH, where I will show how the WHO's theory of health (World Health Organization 1948), though resonating with the aims of empowerment in EBRs, lacks also sufficient precision to be a viable conceptualization of health. For this reason, I will finally turn to a revised version of the HTH (Nordenfelt 1993, 1995, 2001, 2012, *forthcoming*). What I will point out is that this theory can be regarded as a compelling account of health that avoids both the difficulties identified in the BTH and the other version of the HTH, while at the same being compatible with the aims of EBRs. By taking up a fundamental element of self-determination with regard to one's own standard of health, Nordenfelt's (1993, 1995, 2001, 2012, *forthcoming*) holistic theory may constitute the best way to consistently trade-off the value of health with other substantive commitments in the empowerment *bundle* of EBRs.

The Biostatistical Theory of Health (BTH)

The BTH is widely considered the dominant biomedical conception of health (Nordenfelt 1993, Cribb 2005, Tengland 2007, Nordenfelt 2012), and is the most clear-cut example of theories of health to which the 'charge of healthism' outlined above is addressed. The BTH is in fact largely considered an objective, deterministic and value-neutral theory of health (Cribb 2005). In discussing this theory, I will show that we have reasons, independently from its

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[11] Other scholars would no doubt cluster these theories in a different way. For instance, Tengland (2007) argues for the existence of four types of theories of health. Namely, he divides theories into four different monistic kinds: (1) health as functional normality (Boorse 1975, Wakefield 1992), (2) health as balance (Pörn 1984), (3) health as ability (Nordenfelt 1995), (4) health as well-being (1948). In addition, he maintains that also pluralistic theories of health exist, combining two or more features of the monistic ones (Brülde and Tengland 2007). I will make use of the classification proposed by Nordenfelt (2012) for the reason that such broader clustering of theories of health does not leave out any of the theories comprised by the more fine-grained taxonomy of Tengland (2007). As we will see in the analysis of the two types of theories introduced by Nordenfelt (2012), health as balance, ability and well-being can be considered instances of the holistic kind of theories.

compatibility with the empowerment discourse within EBRs, to be cautious before giving this conception of health free reign. In particular, I will argue that strong limitations can be identified in both of the criteria employed by this theory to determine the state of individual or population health.

The most influential example of BTH is the one defended by the American philosopher Christopher Boorse (1975, 1997). The basic idea behind his work is that an organism is healthy, i.e. free from disease[12], insofar as its functioning makes a contribution to its survival and reproduction that is minimally normal in statistical terms. According to the author, evolution has brought about some changes in organisms, but it has also produced "a fixation and conservation" (Nordenflet 1993, 87) of *species-typical* characteristics. Such attributes of organisms are (i) *typical* because they are, in statistical terms, the more frequent functions we can observe in a given organism; (ii) *species-related* insofar as they compose the structure and function of organisms, and serve the goal of survival and reproduction for both individuals and the whole species. The crucial element for this theory is, in other words, determining what natural (i.e. favourable to survival and reproduction) and normal (i.e. statistically more frequent) functions are, so as to discriminate between healthy and unhealthy states in an organism: a problem that, to this view, can be easily solved empirically by turning to contemporary biology and medicine. In the BTH the health of an organism consists therefore of a function of internal processes in the body and their relationship with survival and reproduction. Furthermore, health is a concept "descriptively definable within medical theory" in biological and statistical terms, "as intelligence is in psychological theory or validity in logical theory" (Boorse 1975, 553).

It should be noted that this theory has the merit of capturing some basic intuitions about what constitutes health and its reduction. Pathological conditions (e.g. cancer) can in

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[12] In presenting his theory, Boorse (1975) claims that 'health is the absence of disease'. For this reason, he sets about a conceptualization of health by introducing the concept of disease first. For the sake of simplicity, I discuss here his theory in terms of 'health' rather than starting from 'disease'. It is however not difficult to understand, starting from the formulation of health I present here, what his background definition of disease is. According to Boorse (1975, 1997) a disease is the subnormal functioning (i.e. not making its statistically normal contribution to the survival and reproduction of the individual and the species) of an organ, or part of an organism.

fact be easily recognised as the clear-cut example of processes that reduce our health (i) by impairing the functioning of parts of our body, and (ii) by threatening the survival of the individual. This theory is thus particularly good at capturing those aspects of health that are related to physiological dysfunctions of the body. However, what we should ask ourselves is whether all of that matters with regard to health can be comprised by such a focus. With regard to this point, a number of difficulties have been identified in Boorse's work that have led other scholars to conclude that his theory should be thoroughly refuted as a compelling account of health (Tengland 2007). First, one problem is whether health really requires determining the range of normal functioning of an organism. Especially after the establishment of Personalized Medicine (European Science Foundation 2012), it sounds increasingly odd to hold that for every function or organ of the body there is one normal range that is typical for an organism. Quite the contrary, contemporary biomedicine shows us that normal ranges of species functioning do not exist (if not in the form of abstract generalizations), and that such model of medicine should rather be abandoned in favour of a full uptake of individual unique characteristics determining health. Currently *normal* functioning of a given individual depends rather on the combination (see *infra* Chapter 6) of genetic makeup, age, gender, sex, environment, and lifestyles that draws very little insight from analysing what is typical (i.e. statistically more frequent) for the species. In this respect, Nordenfelt (2012) provides us with a counterexample showing the limitations of this bit of Boorse's (1975, 1997) theory:

> The pulse of an athlete, for instance, can be abnormally low, say thirty-five beats per minute. His or her pulse is then well below the normal frequency scope, which lies between sixty and eighty beats a minute. However, we would clearly say that the function of the athlete's heart is perfect. The function is indeed supernormal in that, as we believe, it makes more than a contribution to the survival of its bearer (Nordenfelt 2012, 26).

This counterexample provided by Nordenfelt shows us that it is not as straightforward as the author claims that normal species functionings are a descriptive and objective attribute of organisms that can be easily established in biological and medical terms. The heart function of the athlete falls outside the scope of statistical normality for a human body, and yet it does not cast any doubt on his/her health status. The establishment of normal and healthy ranges of functioning tells us nothing about health, for the notion of normal ranges makes sense insofar as we relativize it to the circumstances under scrutiny. A criterion for investigating the health of an individual that is much different from Boorse's emphasis on establishing *normal* functioning of a species.

Yet, the criticism discussed so far is not decisive in rejecting Boorse's theory (1975, 1997). His criterion of normal species functioning is nothing but one of the conditions for assessing health. What he could argue in response to the case of the athlete is in fact that the dysfunction he/she bears (i.e. his/her deranging from statistical normality) is still no health problem because it does not lower in any way the probability of survival. However, also this second bit of Boorse's theory proves defective when put to test. Although lots of diseases have the potential of bringing about complications that threaten the survival of the individual affected, it is unclear whether the criterion of reduced survival is able to cover all kinds of diseases "that are conventionally accepted as such" (Nordenflet 2012, 27). Cancer, cardiovascular diseases, are all easy examples to be handled by Boorse's theory. The fact that a tumour or a stroke may lead to death proves, to make an example, that the intuition at the basis of Boorse's second condition is a plausible one. Yet, not all the conditions that we consider diseases are necessarily linked to a reduction of the probabilities of the bearer's survival. Let us consider diseases such as headache, eczema, or injuries like a bruised leg (Nordenfelt 2012). All of these conditions appear to fall under the category of dysfunctions (they derange from statistical normality of human beings), but at the same time they have no known fatal complication that lowers the possibility of survival. This difficulty of Boorse's theory is even more evident if we take into account cases of mental illness such as mild depression. Unless such a depression entails also suicidal tendencies, a person affected by this condition has no possibility of survival that is significantly lower than statistically normal people. This second critique points, in other words, to the limitations – in terms of generalizability – of the second criterion selected by Boorse (1975, 1997) for establishing what disease and health are. Roughly put, the element of survival does not account for all the conditions that we may label as diseases, or health-limiting.

If we combine the latter objection with the one presented above, we can conclude that there are good reasons for scepticism that can be addressed both at the idea of normal species functioning and the idea of survival as viable criteria for health. Furthermore, this recognition points to the need of abandoning conceptualizations of health like the BTH for the foundations of empowerment within EBRs. Leaving aside the charge of healthism, my analysis of the BTH shows that we have compelling philosophical reasons to dismiss the value of the most influential objectivist account of health (Boorse 1975, 1997) in the morality of EBRs. The critical issues identified in Boorse's theory suggest therefore that it may be worth finding a different conception of health, which is able to handle its limitations, to be traded-off with the elements of self-determination and control at the basis of EBRs. In particular, the limitations of the BTH show that, when using the concept of health, our intuitions exceed the mere assessment of functions of the body and its probability of survival. Statistical normality of functions and probability of survival are neither necessary, nor sufficient criteria for assessing health, as the examples of the athlete and the mildly depressed individual show us. But what is it then that makes a person (un)healthy aside from functions and survival? This question is exactly the starting point for theories of health that fall under the category of HTH.

The Holistic Theory of Health (HTH)

Prevalent versions of the HTH build upon the recognition that health cannot be determined from a consideration of functions of parts of an individual. Quite the contrary, health and disease should be understood as phenomena that influence the *wellbeing* or the *ability* of people as a whole in their social context. These theories are thus holistic in two main respects

(Tengland 2007). First, they are holistic because they focus on the whole person either by looking at her wellbeing, or to her abilities. Second, they are also holistic in the sense that they take the environment into account as a relevant factor for health. Both of these elements are, as showed above, far beyond the scope of the BTH. Starting from these premises, it may be already clear to the reader that holistic conceptions of health can be subdivided into two main categories. On the one hand, some versions of the HTH have focused on the element of wellbeing (World Health Organization 1948). On the other, different interpretations of the HTH claim that health is the ability to reach certain goals in a given environment (Nordenfelt 1993, 2012).

The HTH based on wellbeing

The WHO's definition of health can be said to be the most paradigmatic example of a theory that puts wellbeing at its core. Its definition goes as follows: health is a "state of complete physical, social and mental well-being, and not merely the absence of disease or infirmity" (World Health Organization 1948, 1). This version of the HTH has admittedly some strengths. It captures some connotations of health in ordinary discourses, and in particular it has the merit of emphasizing how "there are ideals of health and not merely degrees of freedom from disease" (Cribb 2005, 26). Otherwise stated, it opens up the understanding of the concept of health to the possibility that there exist subjective dimensions of health and that health is also good insofar as it enables individuals to "live their own lives and participate in society" (Cribb 2005, 24). Regardless of the degree of functioning of the body, an individual can in fact be healthy – according to this version of the HTH – if she positively values her quality of life, her fundamental interests are met, and she benefits from fruitful relationships (i.e. her wellbeing is acceptable). Health, under this version of the HTH, is an ideal status that the individual may be able to achieve regardless of her conformity to alleged species-typical standards of functionings.

This is an important consideration in light of the present discussion of the charge of *healthism* within EBRs. The WHO's (1948) HTH may in fact represent a suitable theory to reconcile the conflict between the values of self-determination and health at the basis of the devolution of responsibility EBRs entail (Allen 2011). By pointing to the importance of individual choices with regard to the ideal levels of health to be pursued throughout life, this version of the HTH may guarantee a hierarchy of values between health and responsibility at the basis of EBRs, which does not pay lip service to the empowering aims of these endeavours. If desirable levels of health across society become a matter of individually chosen levels of wellbeing, the charge of healthism is likely to drop because the empowerment step purported by these documents assumes the connotations of an enhancement of individual responsibility to behave accordingly to self-chosen life plans with regard to their health[13].

However, the WHO's theory of health has also been the subject of harsh criticisms since its appearance. As argued by Nordenfelt (*forthcoming*), one set of critiques addressed to this theory has to do with the word 'complete' in its formulation. If we set the threshold to the point that "physical, social and mental well-being" ought to be "complete" (World Health Organization 1948, 1) to count as health, it is likely that most people will fall short of this threshold. The counter-intuitive conclusion to which this theory leads is, in other words, that all people who do not value their life as a complete success would fall under the category of unhealthy people. Most of us are not *fully* satisfied with their physical, social, and mental wellbeing, and yet we would not be keen to conclude that – merely because of that – we all have reduced health. Hence, although it seems reasonable that wellbeing is indeed a relevant component of health, it is at the same time odd to stretch this intuition to the point that the absence of *complete* wellbeing is a state of ill-health.

Furthermore, another limitation of this theory lies in the "difficult task to characterize the well-being purporting to constitute health" (Nordenfelt *forthcoming*, 13). Even if we granted this version of the HTH that the criterion of wellbeing allows for degrees of health, this theory would still result ambiguous as to its specific emphasis on the subjective experience of

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[13] I am fully aware that this conceptual move is not free from defects, as I will argue in conclusion to this chapter. Although giving free reign to individually self-chosen life plans with regard to health has a *prima facie* allure in the context of EBRs, this conceptual move calls for better specifying the criteria under which it is morally legitimate to hold choices regarding the preferred levels of wellbeing "*responsible*". This problem will be the subject of Chapter 4.

health. Stressing the importance of wellbeing as the sole constituent of the HTH entails in fact the risk of equating health with a set of feelings, such as happiness, thus leading this theory to problematic counter-intuitive conclusions. In order to better illustrate this point, let us consider the case of a woman who unfortunately develops breast cancer. At the early stage of its occurrence, such a disease is most likely not to affect the wellbeing of the woman in any respect. If she did not undergo regular mammography screenings, she would be – for a while – completely in the dark with respect to her disease. Her wellbeing is left untouched, at least in the asymptomatic stage of disease development, by the tumour that is growing inside of her. Is it reasonable to claim that the health of this woman is good insofar as she has good feelings with regard to her life? The answer to this rhetorical question is, intuitively, "no" and calls for a rebuttal of the equation between health and wellbeing as the solely relevant dimension of a HTH.

Interestingly enough, the case of the woman in the early stage of breast cancer would not be a problem for the BTH discussed above (Boorse 1975, 1997). Cancer is not part of the normal functioning of humans and threatens the survival of the individual (though prospectively at its early stage), thus allowing us to conclude that this woman suffers from ill-health. This means that there is something valuable, when discussing health, in the focus on the physiological functioning of the body. Yet, we have also seen that this theory has some difficulties in handling conditions that either are not health-diminishing but derange from statistical normality (e.g. the atypical heartbeat of the athelete), or negatively affect health (in the common use of the word) but are not life-threatening (e.g. mild depression). For this reason, I turned to the HTH, and analysed one of its most influent versions (World Health Organization 1948). The merit of this theory is showing how, beside the functioning status of the body, an important aspect of health lies in its subjective dimension. Whether I am in a state of wellbeing or suffering, as to the individual and social goals I wish to accomplish in life, is certainly a relevant consideration for health-related judgements, which is not comprised by the BTH. In addition, we have seen also how this is an important advantage of this theory in the context of EBRs. The WHO's HTH (1948) allows an appreciation of the importance of opening up seizures of responsibility (i.e. opportunities for self-determination) with regard to one's health within the political narrative of EBRs. However, there is an ambiguity in this theory between stressing the importance of wellbeing as a *component* of health, and concluding that wellbeing *is* health. What we need is, in other words, a modified version of the HTH, which is able to capture both the subjective and relativistic aspects of health emphasized by the focus on wellbeing (i.e. the element allowing this theory to avoid the charge of healthism), and the *physiological* aspects of health at the basis of the BTH that may complement the emphasis on wellbeing.

A revised version of the HTH

A theory that responds to these criteria is the one presented by Nordenfelt in its extensive work on the concept of health (1993, 1995, 2001, 2012, *forthcoming*). His version of the HTH can be formalized as follows: "A is completely healthy if, and only if, A is in a bodily and mental state such that A has the *ability*, given standard or otherwise reasonable *circumstances*, to realize all his or her *vital goals*" (Nordenfelt 2012, 24, emphasis added). Three main components of health[14] are emphasized by this theory. First, a pivotal role is played by the concept of *ability*. As we have seen above, different conceptualizations of health have focused on two kinds of phenomena. On the one hand, within the BTH, health has been connected to the functioning of the body (Boorse 1975, 1997); on the other, within one version of the HTH, health has been associated with feelings of well-being (World Health Organization 1948). However, the reason why these two criteria cannot account for a viable conception of health is that they leave out, according to Nordenfelt (2012), what they have in common: namely, the fact that both have consequences on individual *agency*. The distinguishing feature of health-related conditions, such as suffering or being injured, is in fact that they determine what individuals *can* or *cannot* do. Health, in other words, does not depend upon neither

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[14] Despite his thorough criticism of the BTH (Boorse 1975, 1997), Nordenfelt's project (1993, 1995) builds upon a very similar argumentative strategy. He starts from an analysis of health-related concepts such as 'disability' and 'pain'. The reason for this is that, for the author, we often engage in discussions of health due its absence or lack. As in the case of my presentation of Boorse's theory (1975, 1997) and for the same need of simplicity, I will here discuss his theory directly in terms of health, rather than starting from negative health states such as disability and pain.

abnormalities in the body, nor feelings of well-being. Rather, health is a *state* of the individual that lies in his/her ability to achieve some goals.

One question that may be asked at this point of the analysis is whether all kinds of abilities are constituents of health (Tengland 2007). For instance, let us consider my ability to reach the goal of writing a thesis. Is this ability telling something about my health? Even though it is certainly true that achieving this aim is sustained by the ability to move my fingers on the laptop's keyboard, we would not go as far as to conclude that I am healthy only if I am able to write my thesis. And conversely, if I were unable to accomplish such an important goal of my life, we would not reckon my lack of ability to write this thesis as a reduction of health. This means that Nordenfelt's (1995, 2001) theory has to be refined so as to distinguish between health-related and non health-related abilities. The author himself (Nordenfelt 1995) recognizes this problem by differentiating between first and second-order abilities. Abilities, his reasoning goes, "occur in layers, where one layer presupposes the other, but not the other way round" (Nordenfelt 2001, 88). First-order abilities are the upper level of abilities that we can acquire. Driving the car, reading, writing the thesis are all abilities of this kind. Such abilities, that we may call *competences* (Tengland 2007), are not health-related, and presuppose second-order abilities for their acquisition. Namely, "the basic physical and mental resources" (Nordenfelt 2001, 89) that I need to gain a first-order ability. This second level is, according to Nordenfelt (2001), where health lies. This means that I may be unable to write my thesis for two main reasons, and that only one has to do with my health. First I may not be competent enough (i.e. lack the necessary first-order ability) to accomplish the main goal of my PhD studies. This could be due to some limitation in my education, or supervision that would prevent me from writing my thesis. The other one, instead, is that I may lack the second-order abilities (i.e. the health-related abilities) required to do so: I may have a *disabled* sight, or be too frightened and depressed to be able to write my thesis. Only the latter scenario is, according to Nordenfelt (2001), relevant as to considerations regarding my health. Thus, it is better to say that to be healthy is, according to Nordenfelt (2001), to have the second-order ability to reach vital goals. Whether we have the first-order abilities to reach such goals is, in other words, not necessarily a matter of health.

But, what should a healthy person be able to do? This question leads us to the discussion of the second main component of Nordenfelt's theory (1993): the idea of *vital goals*. This expression, coined by the author himself, refers to the state of affairs consciously set by a person, which is a "component of or otherwise necessary condition for the person's living a minimally decent life" (Nordenfelt 2001, 68). Vital goals are, in other words, values, preferences and beliefs that have high priority in our lives. Whether we are able to achieve them (or not) is an important component of our well-being, happiness and satisfaction with regard to our life. Observe here that Nordenfelt is not claiming that health is tantamount to the achievement of vital goals. Quite the contrary, health lies just in the second-order abilities that are required to realize such goals. Or, in the author's own words, vital goals "are constitutive for the healthy person's ability" (Nordenfelt, *forthcoming*, 17). They dictate the set of health-related abilities required for their achievement. Such a relationship between abilities and vital goals allows Nordenfelt to avoid the difficulties we observed in the case of the BTH and the other version of the HTH. First, health-related abilities do not entail any notion of *normality* (Boorse 1975, 1997), thus avoiding one of the major pitfalls of the BTH (i.e. the idea of normal species functioning). It is in fact possible, within this theory, that two individuals who have different second-order abilities are both deemed to be completely healthy. This is due to the fact that these two persons may have different priorities in their respective lives (i.e. different vital goals), and hence need different second-order abilities for their achievement. Their degree of health is relative to the congruence between their abilities and goals, and not by a defined standard of functioning. Second, having positive feelings as to the degree of realization of vital goals does not necessarily entail being healthy, thus avoiding the main limitation of the WHO's version (1948) of the HTH (i.e. the equation between health and well-being). A person who lacks the abilities required for her vital goals could be compensated for his/her disability so that she manages to reach them. Something that is very common among the ordinary activities of healthcare provision. Let us, for instance, think about hearing, visual or walking aids. All of these devices serve the purpose of improving the wellbeing of people who suffer from some disability, by allowing them to accomplish their vital goals regardless of their reduced abilities to do so. Nevertheless, according to Nordenfelt's theory, their lack of second-order abilities required to fulfil such vital goals (e.g. hearing, seeing, walking) would anyway qualify their condition as unhealthy. Differently from theories based on wellbeing (World Health Organization 1948), the individual degree of happiness or satisfaction does not account for all that matters with regard to health.

One final remark needs also to be devoted to the discussion of the third element of Nordenfelt's theory (1993, 2001): the idea of *standard circumstances*. It is evident, according to the author, that health cannot be the ability to reach vital goals under all circumstances. If this was the case, we would be forced to conclude that no individual is ever *really* healthy. Let us consider my (second-order) ability to run. By saying that I am healthy enough to run, we mean first of all that I am in a bodily and mental state such as that I am able to run. Yet, what we also consider as self-evident in this claim, the author argues, is that some standard circumstances obtain in order for this ability to be exercised. And the reason for this is the following. There are a number of conceivable circumstances that could impair my (second-order) ability to run. There could be an environmental factor that prevents me from exercising this ability (e.g. an unexpected snow storm), or I could be physically or legally prevented from moving my body (e.g. being kidnapped, or under arrest). If *all circumstances* – including these exceptional ones – counted in the evaluation of my (second-order) ability to run, and hence of my health, we would be forced to subscribe to the counterintuitive (Nordenfelt *forthcoming*) claim that I am not healthy enough to be able to realize my vital goals. This means that the abilities that constitute health must be related to a certain class of circumstances, and that, claiming that I am able to run, presupposes the existence of what Nordenfelt (1993) calls ordinary or standard circumstances. The author purportedly defines vaguely these external conditions for health. Standard circumstances are of "a personal, cultural and natural kind" (Nordenfelt 1993), and can be considered relative to a cultural situation or context. In the author's own words, the "standard circumstances are not the same for those who live in

Communist China, capitalist Western societies, tropical Congo or Greenland" (Nordenfelt 1993). What a person needs to be able to do in order to pursue her vital goals varies a lot in these very different environments, and so does the resulting conception of what is healthy and what is unhealthy.

It will now be clearer what health is, according to Nordenfelt (1993). It refers to the balance that exists between a person's abilities and the goals of her agency. Full health obtains, from this perspective, when a person is able (i.e. has the second-order abilities) to realise all of her vital goals. Conversely, if this situation is not realized the person maybe considered unhealthy, at least to a certain extent, provided that this judgement relates to standard cultural and environmental circumstances for the individual. This means that health is regarded, within this holistic theory, as an ideal state. Complete health entails, according to Nordenfelt (1993) that the individual can realise *all* of her vital goals. Starting from this ideal, different levels of health are allowed. Whether or not we find ourselves in a state of *acceptable* or *complete* health "is a matter of decision" (Nordenfelt 1993, 96) that depends upon the fulfilment of fundamental requirements established by the individual herself.

Conclusions: Empowerment and the HTH

So far, we have seen how we often oscillate between two different perspectives when discussing health. On the one hand, we think of it as the structure and functioning of separate parts of an organism and, by the same token, we ask ourselves whether everything is *normal* with organs or body functions when making health-related judgements. Such a perspective, which is usually grounded on "biological, chemical and statistical concepts" (Nordenfelt 1993, 86) and is at the basis of what he calls BTH, is however limited – as shown above – in many respects. On the other hand, we also think of health as something that goes beyond – but comprises – the focus on functioning. Health is something broader, according to this view, and resides in a state, or ability of human beings as a whole to pursue their vital goals. By taking up this intuition, we focus on the complete individual and we are interested in understanding whether a person *can* perform all of those activities that make him/her *feeling* *well* with regard to her life. Typically, understanding whether one is healthy under this interpretation requires an investigation of the social and cultural circumstances in which the person establishes her vital goals, and entails an evaluation based on concepts such as "ability, disability, handicap, coping, wellbeing, pain and anguish" (Nordenfelt 1993, 86).

But how does this conception fare with respect to the charge of healthism addressed to EBRs? Is this theory of health compatible with the elements of self-determination and control at the basis of the empowered responsibility prospected by these documents? In order to answer this question, it is worth noting that Nordenfelt's (1993, 1995, 2001, 2012, *forthcoming*) theory of health is widely regarded as advocating for "social and ethical relativism" (Venkatapuram 2012). This means that, very much like in the case of the first version of the HTH analysed above, Nordenfelt's view has the merit of avoiding the charge of healthism because it guarantees a full appreciation of individual sovereignty with regard to what counts as healthy, or unhealthy. What counts as relevant health (i.e. health-related abilities), if we use Nordenfelt's holistic theory in EBRs, is the result of the responsible choice of a set of vital goals by the empowered citizenship these policies prospect. This recognition, as it stands, solves the charge of healthism. Health is not an objectivist set of functionings to which the individual is expected to conform. However, Nordenfelt's theory may raise another issue in the ethical appreciation of EBRs.

Although most of his critics (Tengland 2007, Venkatapuram 2012) agree that this reasoning represents a coherent understanding of the concept of health, the fact that his theory envisages health as an ideal that the individual establishes for his/her standard environment represents in fact a conclusive reason for scepticism. Simply put, critics argue that assessing whether a person is healthy or not cannot be just a matter of subjective judgement, and that, in doing so, Nordenfelt's account runs the risk of forgetting that social arrangements can be sometimes detrimental to the individual establishment of vital goals and the abilities constituting health (to use his own language). Otherwise stated, though avoiding the charge of healthism, Nordenfelt's subjectivism and relativism as to what constitutes health entails another danger. Namely, the risk that individual conceptions of health may be determined by local conditions and practices that would obscure what we may consider as ill health resulting from social injustice. An outcome of this theory may be the undesirable consequences of considering *all* choices with regard to the chosen levels of health to accomplish in one's life as *equally* responsible, thus ignoring the effects of social arrangements on those who are powerless, or suffer from endemic disadvantage in our societies (Venkatapuram 2012).

With regard to this potential unwanted consequence of using Nordenfelt's relativism in the context of EBRs, I maintain that it represents no sufficient ground to disqualify his theory. Pointing to the risk that people may adapt to unfavorable circumstances – and that by doing so their self-evaluation of health will necessarily be distorted (Elster 1982) – represents only a good reason to look at how individuals *choose* their vital goals and health, and not to dismiss a subjective understanding of what counts as relevant health. Otherwise stated, the fact that the conditions under which these choices take place may not satisfy substantive criteria of responsible agency (Minkler 1999, Wilkinson 1999, Buyx and Prainsack 2012, Brown 2013), tells nothing about whether health should still reside in a subjective judgement. Rather, it calls for establishing what are the relevant criteria under which *responsible* choices with regard to one's vital goals – and consequently as to the health-related abilities required for their achievement – ought to take place.

The analysis of the substantive criteria for such allegations of responsibility, useful to the context of EBRs, will be the subject of the next chapter of this thesis. As to the present analysis of health, it is instead important to stress how, differently from the BTH (Boorse 1975, 1997), both versions of HTH (WHO 1948, Nordenfelt 1993, 1995, 2001, 2012, *forthcoming*) are able to circumvent 'the charge of healthism' addressed to EBRs (Minkler 1999, Greenhalgh 2004, Veitch 2010). Holistic accounts of health privilege the subjective dimensions of health, and point to the necessity of framing its value as relative to the individual perspective, values, and life goals. For this reason, it is possible to conclude that both of these theories constitute *prima facie* suitable accounts of health for the purpose of establishing the substantive foundations of empowerment in EBRs. Yet, the difficulties identified above in the WHO's version of the HTH point to the need of abandoning this theory due to its limitations in capturing some of the relevant dimensions of health (i.e. the necessity to distinguish health from broader wellbeing). Starting from this recognition, I then proposed the Nordenfeltian account as a revised version of the HTH that both manages to avoid the charge of healthism, and the philosophical objections that apply to its WHO's interpretation. Just as Nordenfelt's HTH (2012) has come to regard health as one of the means of achieving the vital goals that make life socially and culturally productive, empowerment within EBRs should act "instrumentally to facilitate 'healthy' decision-making" (Tones 1998, 71) in the sense of fostering responsible decision-making with regard to one's vital goals and their pursuit. By resorting to a conception of health like Nordenfelt's HTH (2012), EBRs could commit to the values of self-determination and control allegedly at the basis of their diffusion of responsibility for health, while at the same time evading the adoption of an inadequate understanding of health. By linking Nordenfelt's theory of health (1993, 1995, 2001, 2012, *forthcoming*) to the broader aims of EBRs, the establishment of vital goals depends upon the empowered *and* responsible choice of individuals and so does, by the same token, the set of abilities constituting health required for their achievement.

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Chapter 4. Responsibility for health beyond *choice*: an empowerment approach

Introduction

In the previous chapter, I have discussed how different conceptions of health can have a bearing upon the ethical evaluation of EBRs. What I showed is that the elements of self-determination and control at the basis of empowerment support the view that EBRs should be grounded on an understanding of health that is *relative* to "patient's (or group's) interests, benefits, or quality of life" (Cribb 2005, 27). To this end, I argued in favour of Nordenefelt's 'holistic theory of health' (Nordenfelt 1993, 1995, 2001, 2012, *forthcoming*) as a suitable theory of health for empowerment within EBRs. Such a view, I showed, has the advantage of avoiding a charge of *healthism* addressed to EBRs.

Yet, this conclusion led me to a second aspect of appeals to responsibility for health within EBRs that has indeed already fostered many criticisms. Many of these policy documents recommend in fact citizens to be responsible for their health and with respect to their use of healthcare resources. Such shift in responsibility for health is presented as a core tenet of the broader *empowering* intent of putting individuals "at the heart" (Great Britain 2004a, 2004b) of the healthcare system, and raises questions about the interpretation of responsibility that are of utmost importance for the ethical appraisal of EBRs. As we will see in the present analysis, different interpretations of responsibility for health allow invoking different ethical or critical evaluations of EBRs. It is thus crucial to address such confusion so as to anticipate the concerns fostered by EBRs and their emphasis on responsibility for health.

This critical appraisal of EBRs grounded on the negative aspects of 'responsibilization' for health stresses the difficulties of assuming that people can be rightly held responsible for their health (Minkler 1999, Wilkinson 1999, Buyx and Prainsack 2012, Brown 2013). From this perspective, the main problem with EBRs is not that they invoke responsibility for the promotion of a particular standard for health across the population (see *infra* Chapter 3).

Rather, it is the assumption that agents are *sufficiently free so as to be in charge of their health-related choices*. An uncritical attribution of responsibility for health that does not take into account this issue, critics argue, simply ignores the variety of social constraints having an impact upon individual capacity for health-related decision-making, and hence may constitute illegitimate ethical ground for allegations of responsibility with regard to one's health. Extensive evidence (Marmot and Wilkinson 2005) has been in fact produced regarding the socio-economic gradient of health. Roughly put, this evidence shows that the lower the socio-economic status of an individual is, the higher the likelihood that she will experience poorer health outcomes. This is mainly due to differences in power, skills and resources within a given population, and implies that shifting responsibility from the system onto the hands of patients could disempower rather than empower certain groups of our society. Since unhealthy behaviours are less about personal control than EBRs assume, a devolution of responsibility for health failing to recognise that it does not fall within everyone's powers to refrain from risky behaviours, may accentuate or introduce health inequalities in the general population.

This is the main reason why the 'responsibilization critique' calls for a critical scrutiny of normative approaches to responsibility for health within the context of EBRs. In order to address this issue, this chapter of the thesis will proceed as follows. First, I will review the main arguments in favour of holding individuals responsible for their health. As to this matter, I will distinguish between appeals to responsibility for health grounded on its 'backward-looking' and 'forward looking' interpretations, and show how different normative perspectives – ranging from luck egalitarianism to consequentialism – may uphold a number of conditions for normative claims of responsibility for health within EBRs (Morreim 1995, Cappelen and Norheim 2005, Feiring 2008, Segall 2009, Voigt 2013). Second, I will present three main objections against such appeals to responsibility for health. I will discuss (i) a general argument against the normative relevance of the dichotomy between 'backward-looking' and 'forward looking' understandings of responsibility for health (Albertsen 2013), (ii) a solidarity-based rebuttal of individual responsibility for health (Buyx and Prainsack 2012), and (iii) an argument questioning the notion of 'freedom of choice' at the basis of attributions of responsibility for unhealthy behaviours (Brown 2013). In light of these objections, I will conclude that we have convincing reasons to question the moral assumptions on which appeals to responsibility in healthcare are grounded (i.e. the idea that we can deem individuals to *freely choose* health-related behaviours and lifestyles) and, consequently, to prefer EBRs not to be grounded on any of such normative stances.

Starting from this recognition, I will then move to a possible foundation of appeals to responsibility for health within EBRs. I will show that empowerment theorists approach matters of responsibility for health-related behaviours (Koelen and Lindström 2005), from the assumption of a distinct view of human agency in healthcare. Consequently, the empowerment perspective on responsibility for health can primarily be regarded as questioning the notion of freedom and responsibility (Brown 2013) at the basis of most of the approaches currently dominating the debate. The case for attributions of responsibility for health starting from the premises of empowerment is rather concerned with a different view of what it means to be responsible in the first place. Some interpretations of empowerment underscore in fact what can be called an *ecological* model of responsibility for health. This model points to the necessary "balance between individual self-efficacy and broader political […] action for social change" (Minkler 1999, 132) for legitimate attributions of responsibility for health. In other words, the empowerment perspective on responsibility for health does not necessarily entail abandoning the endeavour of devolving responsibilities for health to citizens. Quite the contrary, appeals to responsibility for health can be grounded on the substantive views of empowerment approaches to health promotion. However, such views demand a framing of individual responsibility within the context of social responsibility for health, thus pointing to a set of social conditions to be met in order for ascriptions of responsibility to be lawful. Without attending to the broader *inter*-personal level of determinants of health (e.g. political opportunities for organizational change and community development), no emphasis on *intra*-personal change can have ethical ground from the perspective I will defend throughout this chapter.

It is against this background, I will conclude, that appeals to responsibility for health within EBRs could avoid the 'responsibilization critique' outlined above. This framing of responsibility for health has in fact the merit of shifting the focus of its assessment towards the issue of whether individual capacity, *together* with its broader social environment, are such that they empower the individual to be substantively responsible for her own health. Rather than being a matter of individual liability for *choice*, responsibility for health – through the lens of the *ecological* model – calls for the more fine-grained analysis of the contribution of socioeconomic structures on freedom and responsibility for health demanded by critics of EBRs.

Different kinds of appeals to responsibility for health

In recent years, the notion of individual responsibility for health has received a great deal of attention in philosophical debates (Minkler 1999, Wilkinson 1999, Feiring 2008, Buyx and Prainsack 2012, Albertsen 2013, Brown 2013, Voigt 2013). As mentioned above, many scholars agree upon the difficulties of holding individuals responsible for their health. Yet, the reasons behind this conclusion are a vexed matter and depend upon how we interpret appeals to responsibility as to health-related matters (Wikler 1987). Powerful normative arguments can in fact be found in the literature to stress the importance of individual responsibility in healthcare. In particular, these appeals to responsibility for health are grounded on two[15] distinct notions of responsibility (van de Poel 2011). The first one is a 'backward-looking' notion responsibility, i.e. the idea that holding a person responsible means that such person is properly accountable (subject to praise or blame) for having acted in a certain way. The second is instead the 'forward-looking' notion of responsibility, pointing to the idea of responsibility as substantive claims about whether people's actions can be regarded as depending on and reflecting their choices.

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[15] Voigt (2013) identifies a third kind of appeals to responsibility for health. Namely, those connecting such appeals to wider considerations of efficiency for the system (Great Britain 2004, 2010a, 2010b). From this perspective, the responsible citizen is not only the one who takes up control over his/her health, but also the one that contributes to the sustainability of the healthcare system with his "healthy behaviours". For a discussion of this kind of appeals to health, see: *infra*, chapter 3.

In the remaining of this section, I will briefly outline different arguments that, building upon the two notions of responsibility outlined above, have provided reasons in favour of allocating responsibility for health at the individual level. As we will see, both arguments based on backward-looking responsibility (the luck-egalitarian and the liberal egalitarian), and arguments grounded on forward-looking responsibility (liberal-contractualist and consequentialist) come in two main versions.

Backward-looking responsibility

The first account of backward-looking responsibility is concerned with finding a criterion for rationing the allocation of healthcare resources (Segall 2009). Such a view, which has been widely ascribed to luck egalitarians (Segall 2009, Voigt 2013), stipulates health inequalities to be "fair if and only if they are the result of choices for which agents can be held responsible" (Voigt 2013, 147). This means that, conversely, only those inequalities arising from brute luck (i.e. from circumstances that are beyond individual control) should be considered as problematic. Starting from these premises, luck egalitarians support claims of responsibility for health by arguing that patients should be held liable for their additional demand of healthcare resources when such costs are the result of their own choices. In particular, those who suggest that responsibility should serve as criterion for denying a treatment, or according lower priority, or requiring a higher contribution to patients and clients, often take as an example lifestyle-related illnesses. Since most of these diseases are the result of individual choice and behaviour, this line of reasoning goes, we do not have reasons of justice to include their treatment and management in the provision of publicly funded healthcare services. The additional burden on those who are suffering from a disease that is caused by their own choices (e.g. smokers) is not in fact problematic from the point of view of justice, because it is the result of choices for which individual agency can be held responsible.

A second and distinct kind of appeals to responsibility, based on its backward-looking understanding, comes instead from the normative perspective of liberal egalitarians (Cappelen and Norheim 2005). Liberal egalitarian theories of distributive justice maintain that public policies should aim at securing equal opportunities for all individuals, which in turn require the elimination of all sources of inequalities that "arise from factors outside the agent's control […], such as a person's natural and genetic abilities" (Cappelen and Norheim 2005, 478). Similarly to luck egalitarians, therefore, liberal egalitarians deem inequalities or costs that are the result of individual choice as acceptable, and conclude that people should be held responsible for their health-related choices. Yet, a main difference exists between luck and liberal egalitarians. While luck egalitarians go as far as considering the *choices* of individuals sufficient ground to ascribe them the burden of their *consequences*, liberal egalitarians draw a distinction between choices and consequences that has strong normative relevance. To hold people responsible for the actual consequences of their choices would in fact be too much for the liberal egalitarian because the outcomes of individual choices depend also on other factors. Some people, they argue, are lucky when they entertain risky behaviours, while some others are not. This means that the difference between, say, a lucky smoker and an unlucky one (i.e. the one who develops cancer, and the one who does not) is not dictated only by their own respective choices – which is indeed the same (i.e. engaging in the risky habit of smoking) – but rather from factors that are beyond their control and that can be regarded as luck. For this reason, liberal egalitarians reject the view supported by luck egalitarians that health costs resulting from individual choices (e.g. unhealthy lifestyle, or risky habits) should fall on the individual. The correct place to introduce responsibility, they argue, "is not at the sick bed" of the individual (Cappelen and Norheim 2005, 479). Rather, responsibility should be allocated on choices, through mechanisms that reward healthy behaviours (e.g. tax deduction for sport activities), or disincentives that render less appealing the unhealthy ones (e.g. taxation of goods such as cigarettes or alcohol).

Forward-looking responsibility

Claims of responsibility for health based on its 'forward-looking' interpretation have to do instead with the emphasis put on strategies to encourage individuals to take up responsibility for their health (Feiring 2008). Rather than looking at whether individuals can be held substantively responsible for their previous choices, attributions of responsibility should concern the willingness of individuals to change their future behaviour. In its liberal-contractualist interpretation, arguments from 'forward-looking' responsibility drift the attention away from the question of determining whether the individual is responsible for the bad consequences (in terms of health) of her actions. What matters as to responsibility attributions is whether the individual is ready to "sign a contract declaring a commitment to undertake medical follow-ups and other activities aimed at changing the lifestyle in question" (Albertsen 2013, 2). It is only after the individual is given the opportunity for such a commitment that healthcare resources should be allocated on the basis of responsibility. The reasons for giving up on claims of substantive responsibility for previous choices are manifold, according to the proponents of this view. First, it is always difficult to determine whether something has happened because of deliberate choice or because of the circumstances. Keeping the two distinguished requires in fact an explanation of "what is to count as a choice and what is count as circumstance that must be acceptable to all" (Feiring 2008, 35): a conceptual endeavour that seems problematic "in ideal theory" (Feiring 2008, 35) as well as in practice. Second, establishing whether some health disadvantage can be attributed to choice or circumstances may be intrusive for the privacy of the concerned individual, or even further ignite a culture of "moralised judgements in order to classify persons according to the degree of irresponsibility of their choices" (Feiring 2008, 35). Thus, it is better abandoning the focus on responsibility as past choices, and rather to reframe the discourse as an opportunity for a "fresh start" (Vansteenkiste et al. 2014) with regard to unhealthy lifestyles and future health improvements.

A second kind of arguments from 'forward-looking' responsibility is grounded instead on consequentialist normative theories, like utilitarianism (Morreim 1995). Very much like the liberal-contractualists, utilitarians are not interested in liability for past choices. Rather, their attention to responsibility aims at maximising choices with the best consequences for the highest number of people. This means that solving normative matters of responsibility is not an end in itself for the consequentialist. Rather, the promotion of responsibility is just regarded as a means to the end of encouraging behaviours that maximise health and wellbeing in the population. Starting from these premises, the consequentialist is mostly concerned with the reason why individuals engage in risky behaviours. According to this view, the problem with the healthcare system is that it favours the same kind of behaviours it wishes to limit. Citizens are inclined to undertake hazardous lifestyles because they do not personally face the consequences of the additional burden that their unhealthy behaviours put on society (in terms of costs). Contemporary healthcare is, in other words, a regime of *moral hazard* in need of practical strategies that, by changing individual behaviour, can produce the best consequences for the collectivity. Preeminent among such strategies, scholars argue, is the role that economic incentives could play to compel individuals to caring about, and thus ameliorating their health. Both negative and positive incentives have in fact the merit of linking distribution of costs or treatment to behaviours, by making *hazardous* lifestyles less appealing for citizens, and at the same time maximising instances of appropriate and healthy choices.

A critical appraisal of appeals to responsibility for health

Determining whether EBRs are grounded on any of the appeals to responsibility for health described above is no easy task. In most of the cases, these documents display a vague and underdetermined endorsement of substantive claims of responsibility in healthcare. And probably, I shall add, it is precisely such lack of clarity that has been often regarded as a source of ethical, social and political concern by their analysts (Veitch 2010, Colombo et al. 2012). Yet, in this section I wish to make the following point as to the normative perspectives that, within EBRs, could justify holding individuals responsible for their health. Regardless of which of the four accounts outlined above EBRs endorse, the moral reasons against upholding each of them are sound, and call for a different understanding of responsibility as a normative basis for the implementation of this new healthcare model.

In order to ground this claim, I shall distinguish among three different objections to appeals to responsibility for health. First, an argument against them has to do with the moral relevance of the distinction between past and future choices (Albertsen 2013). Second, another kind of criticism of appeals to individual responsibility comes from solidarity-based approaches to healthcare policymaking (Prainsack and Buyx 2011, Dawson and Verweij 2012, Buyx and Prainsack 2012). Third, appeals to responsibility for health can be dismissed by questioning the idea that individuals act *freely* in determining their own lifestyle, and thus can be deemed responsible for engaging in unhealthy behaviours (Brown 2013).

On the moral significance of the distinction between 'forward-' and 'backward-looking responsibility

The implications of distinguishing 'forward-looking' and 'backward-looking' arguments in favour of responsibility, have led some scholars to conclude that the two perspectives often coincide and that the distinction between past and future choices offers less normative ground than its proponents think (Albertsen 2013, 2). In particular, this critique claims that the 'forward-looking' *vs.* 'backward-looking' dichotomy leads to counterintuitive and inconsistent conclusions that fundamentally undermine its moral importance for normative matters of responsibility for health. In order to better illustrate this point, Albertsen (2013) builds upon an example borrowed from the seminal work on responsibility by American philosopher Thomas Scanlon (1998, 256-258):

> The local town council is tasked with the removal of hazardous waste. The health risks of leaving it would be huge, but removing it involves a much smaller although significant health risk (i.e. chemicals evaporating into the air during transport). The town council does as much as could be expected of them in notifying citizens prior to the event, and in shielding the relevant digging sites. Person C receives the information and chooses to travel to the site, climbs the fence and gets sick as a result. (Albersten 2013, 2)

The issue raised by this example is obviously whether C should be regarded as responsible for the health consequences of her hazardous behaviour. A positive answer to this question is a cakewalk from the perspective of a backward-looking account of responsibility. Regardless of whether we endorse its luck egalitarian or liberal egalitarian interpretation it is indeed quite straightforward that C should be held responsible either for the sickness, or for the choice of exposing herself to the risk of getting sick. C has in fact voluntarily crossed the fence, and the outcome is the by-product of circumstances on which C had control. Things stand differently, however, if we look at this case from the perspective of forward-looking interpretations of responsibility. On a liberal-contractualist account C would not be deemed responsible for the consequences of such a hazardous behaviour. Since she had not taken any previous commitment to refrain from this risky exposure, she could not be deemed responsible for the health-related consequences of her choice. The same kind of conclusion can be as well drawn from a consequentialist point of view. Since no incentive that could encourage C to avoid crossing the fence was in place, the responsibility for the consequences of her hazardous behaviour cannot fall, neither retrospectively nor prospectively, on her.

This situation exposes some of the counterintuitive consequences of holding the 'forward-looking' *vs,* 'backward-looking' dichotomy as a relevant criterion for normative issues of responsibility for health (Albertsen 2013). In particular, it could be argued, it displays the weaknesses of its 'forward-looking' interpretations, and questions the difference of such accounts with those grounded on 'backward-looking' responsibility. The reason for concluding this lies, as we have seen above, in the fact that the moral foundations of responsibility on all of these accounts have to do with the question of whether the individual can be held responsible for her own choices. Though starting from different premises, the main condition that for all of them "must be in place before a person can be said to be responsible for a state of affairs" (Albertsen 2013, 3), is whether the individual has the capacity to be considered the author of her own choices (Scanlon 1998). In the case of C we have very strong reasons to think that she acts voluntarily and responsibly when exposing herself to the hazardous waste. She explicitly chooses to travel to the site, cross the fence, and maximise her risk to get sick as a result of an exposure to hazardous substances. And yet, the sole fact that no previous commitment or incentive was in place, in order to make her avoid such exposure, obliges us to conclude that she is not responsible for her risky behaviour.

Whether or not she acts in full autonomy and freedom, or whether she can be reasonably held responsible for her actions has no moral import over judgements of liability and accountability from the perspective of 'forward-looking' accounts. Her action is valued differently depending on matters of time and economic incentive, which add very little to the moral legitimacy of judgements of responsibility.

For this reason, I side with Albertsen (2013) in concluding that it seems counterintuitive to restrict ascriptions of responsibility on the basis of the time at which individual choices occur. And I add that the same applies to the existence of economic incentives for healthy behaviours. Distinguishing between actions that are morally relevant in terms of responsibility means looking at the conditions in which individual choice took place or will take place, investigating whether it is ethically legitimate to hold the individual accountable for a certain act. This points to the importance of assessing whether the individual has the capacity to be deemed responsible for her actions, whether the individual acts *freely* in *determining* a certain state of affairs. Normative matters of responsibility for health are, in other words, neutral on the subjects of time and economic incentives, thus granting us reasons to give up on the moral value of the 'forward-looking' *vs,* 'backward-looking' distinction. Quite the contrary, both of these kinds of appeals to responsibility for health should be evaluated – as I will do in the next sections of this chapter – by scrutinizing the moral reasons that make us consider agents substantively responsible for their choices.

A solidarity-based rebuttal of appeals to responsibility in healthcare

A second kind of criticism to appeals to individual responsibility for health builds upon the recent attention that bioethical debates have devoted to the value of solidarity in healthcare policymaking (Prainsack and Buyx 2011, Dawson and Verweij 2012, Buyx and Prainsack 2012). In the understanding of its proponents (Prainsack and Buyx 2011), solidarity can be defined as the "shared practices reflecting a collective commitment to carry 'costs' (financial, social, emotional or otherwise) to assist others" (Prainsack and Buyx 2011, 46). Solidaristic acts and practices are, in other words, not only individual expressions of sympathy towards others' vulnerability in which we recognize our own. Quite the contrary, solidarity often manifests itself in the form of solidified social norms and structures (e.g. welfare systems and social welfare arrangements) that represent an explicit societal commitment to assist others at a nominal cost for each member of a society. For this reason, the solidarity-based rebuttal of individual responsibility for health is mainly addressed at arguments of retributive and distributive justice as to resource allocations. In particular, the main types of argument that this view addresses are the ones claiming that, since people can be held accountable for the health risks produced by lifestyles, they should withstand the additional health costs of their behaviour either by limiting their access to health care services, or by modifying their insurance coverage, or by applying fines to the hazardous behaviour at stake.

With regard to this matter, the line of argument of solidarity scholars starts from a critique of the notion of 'risk' at the basis of appeals to responsibility for health (Buyx and Prainsack 2012). One of the premises of such arguments, they argue, is that increased health risks are *determined* by individual behaviour. Yet, such a view is deemed simplistic and "misconceived" (Buyx and Prainsack 2012, 82) for one main reason. Namely, it is far more challenging than it is assumed by its proponents that a *causal* link exists between unhealthy lifestyles and increased risk to develop a certain disease. Judgements of causality are indeed, according to the authors, subject to conditions of uncertainty that undermine their moral import on claims of responsibility for health. Although the available evidences from epidemiology and public health show us that behaviours are an influential risk factor in the general population, when it comes to determining the causes of a given condition it is often extremely difficult – if not impossible – to ascertain how individual choices produce disease-specific patterns of risk. The understanding of health risks as the result of individual lifestyles overlooks therefore, according to this view, the importance of other factors contributing to disease development. Decades of research in genetics and genomics have shown in fact that most health conditions are the result of the interplay of heritable and non-heritable factors. In particular, recent developments in epigenetics support the view that disease aetiology (with the notable exception of genetic disorders such as cystic fibrosis, or Huntington's disease) is in large part multifactorial (Petronis 2010, Meloni and Testa 2014), and involves environmental influences, individual biological make-up and lifestyles alike. Behaviours are, in other words, only *partly* the causal factor of the vast majority of diseases. Hence, since we are not in the epistemic condition of pinpointing the precise causal relation between lifestyles and health risks, we should reject individual responsibility as a criterion for the allocation of resources in healthcare.

Building upon this analysis of risk stratification, the proposal of solidarity scholars is to recast normative matters of responsibility for health in a different language from that of risks. In particular, they argue, the alternative of a solidarity-based approach would prescribe access to healthcare services to be granted on the basis of individual *needs* rather than desert, or stratification of risks related to lifestyle. 'Need' is in fact, according to their view, a category that well represents the 'sameness with others' at the basis of their understanding of solidarity, and that "can empirically be determined far more easily" (Buyx and Prainsack 2012, 83) than lifestyle-related patterns of risk. The normative exercises that fall within the scope of solidarity are, in other words, diametrically in conflict with those of the appeals to responsibility for health abovementioned. First, the difficulties they identify in this line of argumentation lie in the assumption that it is possible to delineate the causal link existing between individual lifestyle and health risks. Rather, what solidarity scholars show us is that systems for the stratification of risks are often limited in their scientific foundations. By doing so, they question the main tenet of the accounts of responsibility for health enumerated above. Regardless of whether individuals can be considered to act freely in choosing their lifestyles, solidarity scholars rightly point out that behaviours are only one among the factors that concur to the development of diseases, and that, for this reason, we should downplay the moral importance of responsibility for health in regulating the distribution of healthcare resources. In addition, their contribution has also the merit of pointing to an important – yet overlooked – source of normativity for ethical matters of responsibility for health. Namely, the repertoire of practical, interpersonal and legal manifestations of our reciprocal commitment to support and help our fellow citizens that goes by the name of solidarity.

A freedom-based rebuttal of appeals to responsibility in healthcare

Finally, a third kind of objection to appeals to responsibility for health has to do with the key assumption of these arguments we identified above: namely, the idea that individuals act *freely* in determining their own lifestyle, and thus can be deemed responsible for engaging in unhealthy behaviours (Brown 2013). This criticism, which I shall call 'the argument from (lack of) freedom' claims that choosing between candidates for the allocation of healthcare resources cannot be justified on moral grounds of freedom and responsibility for lifestyle choices. In particular, Brown's proposal (2013) is to evaluate the legitimacy of claims of desert and blameworthiness as to health-related behaviours on the basis of Pettit's account of freedom as 'fitness to be held responsible' (Pettit 2001). If, starting from this account, individual can be said to lack freedom when making lifestyle decisions, this implies straightaway that we should not consider them responsible for what they do. For this reason, Brown introduces some of the requirements that Pettit identifies for ascriptions of freedom to agents. According to the author (Pettit 2001), there exist three main domains in which freedom of agency is at stake. First, predicating freedom of an agent is to recognize the agent's *responsibility* for a given action. This means that we hold an individual free insofar as we can safely assume that she authored a given act on a given occasion, i.e. her actions are indeed the result of her will. Second, freedom pertains to actions in which we can recognize the agent's *ownership*. Namely, an individual acts freely to the extent that she reflectively endorses the action under scrutiny, i.e. she thinks: "this bears my signature, this is me" (Pettit 2001, 6). Third, freedom comprises the recognition that no influence from the environment can be regarded as *determining* choices of agents. In this respect, free agency is qualified by the lack of external influences undermining the possibility to choose among significantly numerous and distinct options available (Pettit 2001, 66).

Pettit's account has the explicit goal of providing a unified picture of 'freedom' that takes into account its dimensions of responsibility, ownership, and determination by external influences (Pettit 2001). In particular, his aim is to show how these three distinct domains are intertwined and concur to determine whether we can consider an agent to be free, or fully fit to be held responsible. A failure in any of these three domains of freedom can be in fact regarded, according to Pettit, as sufficient ground to dismiss (or at least relieve) individuals from claims of responsibility:

> When will freedom in this sense fail? Intuitively, you will not be fully free in respect of a choice between A and B, if you are not aware of the availability of […] options in your environment of choice, do not have the conceptual resources to evaluate them, or are not functioning in a way that would allow that evaluation to affect what you do. You will not be free if, as a self, you are subject to problems that make it impossible for you – or just particularly difficult for you – to claim A or B as something you did. And you will not be fully free if, as a person, you are the victim of an unwelcome form of pressure or duress or coercion that makes it more difficult to do one or other [thing] (Pettit 2001, 13-14).

Starting from these premises, Brown's (2013) objective is to show how these failures of freedom obtain when dealing with claims of responsibility for (un)healthy behaviours. To this aim, she then introduces extensive evidence on the so-called 'social determinants of health' and the psychology of health behaviours. Such knowledge, pointing to the sensitivity of population health levels to social environment and arrangements (Marmot and Wilkinson 2003, World Health Organization 2013), undermines in fact ascriptions of free agency in each of the connotations identified by Pettit. First, literature on the social gradient of health shows us that individuals may not satisfy the criterion of *responsibility* identified by Pettit (2001). In particular, bits of evidence in health psychology – suggesting that individuals from disadvantaged backgrounds are more susceptible to the detrimental environmental influences yielding compulsive and addictive behaviours – appear to undermine the claim that unhealthy behaviours are the result of free will. Quite the contrary, the higher likelihood of people with low socioeconomic status to entertain addictive or compulsive behaviours points to the role of external influences in precluding – at least to a certain extent – the capacity to act in healthier ways. The plethora of influences and environmental cues that characterize the most deprived settings in our society deflates, in other words, claims of causal responsibility for unhealthy behaviours. Contrary to what is upheld by responsibility-sensitive approaches to resource allocations in healthcare, most of these actions are most likely *not* an expression of free will.

Second, another way in which broader environmental considerations affect our ascriptions of freedom and responsibility has to do with matters of identification and *ownership* of unhealthy behaviours. As shown above, one of the fundamental requirements for freedom of action on Pettit's account lies in what he calls the discursive control over the action. To be free in performing a certain action, I must identify such act as "distinctively and intimately mine" (Pettit 2001, 7). This means that actions such as responses, choices, behaviours are free insofar as they conform to long-term desires and goals of an agent. This kind of requirement for free agency, Brown argues (2013), is far from being satisfied when we take into consideration the psychological mechanisms at the basis of unhealthy behaviours. Most of the time, these acts are of habitual nature, meaning that they are often performed without the control of conscious reasoning, and would require a great effort on the side of the individual to be changed. Typically, this makes lifestyle behaviours permeable to influence from the social context (e.g. advertising, others engaging in unhealthy behaviours) that hinders the capacity of agents to exercise a rational control on them. Even though individuals may have a strong desire to refrain from unhealthy lifestyles (e.g. the reluctant smoker), it is likely that their reiteration does not pertain psychological mechanisms of control and ownership, thus failing to satisfy the second condition for free agency established by Pettit (2001).

Finally, the third requirement for free action on Pettit's account (2001) pertains to the lack of significant external influences and pressure for a given behaviour. Recall that, in his view, ascriptions of freedom are legitimate when actions are under-*determined* by the myriad of "coercive and quasi-coercive ways" in which social arrangements may "intrude upon a person" (Pettit 2001, 66). With regard to this point, it could be useful to refer to the extensive evidence on the causal pathway that links social deprivation and exclusion (e.g. poverty, unemployment, disadvantaged upbringing) with poor levels of health and reduced life expectancy (Marmot and Wilkinson 2003). In particular, the robust two-way pathway identifiable between addiction to alcohol or tobacco and social deprivation can better illustrate here the point raised by Brown (2013). People are in fact more likely to turn to alcohol and tobacco if they come from a poor background, and alcohol and tobacco dependence are likely to lead individuals to downward social mobility (Marmot and Wilkinson 2003, 24). This means that socioeconomic status and background can be consistently shown to yield deleterious effects on the third dimension of freedom in Pettit (2001). Roughly put, the social gradient of health jeopardizes the social component of freedom by highlighting how individual behaviours are subject to determination from external influences and pressures.

The application of Pettit's theory of freedom (2001) allows Brown (2013) to operate an assessment of responsibility for health, which is radically different from the arguments analysed in the previous section. Her account problematizes the fundamental premise on which most of appeals to responsibility for health are grounded: namely, the idea that claims of responsibility for (un)healthy lifestyles can be defended on moral grounds of freedom in performing those actions. Building upon Pettit's inquiry (2001) on the substantive foundations of freedom and evidences of the social determinants of health, she questions these accounts at the very basis by dismissing the moral legitimacy of appeals to responsibility for health. Knowledge of the social patterning of health suggests in fact a rather different view. In the words of epidemiologist Leonard Syme, this knowledge points to the fact that "as individuals we *are* ultimately responsible for our own health. But it is naïve to think that we are free agents in this. All of us are influenced by forces in the community that shape our choices and preferences" (Syme 1994, 82).

Interim conclusions

In this section we have encountered different reasons for holding problematic responsibility-sensitive theories for the allocation of healthcare resources, which could potentially drive the implementation of EBRs. First, we have seen how the distinction between 'forward-looking' *vs.* 'backward-looking' accounts is wanting closer philosophical scrutiny as to its relevance for the normative appraisal of responsibility claims. Building upon Albertsen's analysis of the liberal-contractualist perspective, I showed that the existence of economic incentives, as well as the time at which an action takes place, provides no moral ground for appeals to responsibility for health, and that therefore the 'forward-looking' *vs.* 'backward-looking' dichotomy should be rejected. By showing this, I concluded that the legitimacy of responsibility claims depends upon the substantive criteria for holding individuals accountable for their behaviours. From the perspectives discussed above, a person is held responsible, once we recognise that the forward- backward-looking distinction does not hold water, because she is deemed to have voluntarily chosen to expose herself to a given health risk, and not because of the time or the incentives that contribute to the action performed.

With regard to such substantive criteria of responsibility, I then discussed two possible strategies for their rebuttal. On the one hand, I showed how solidarity scholars (Buyx and Prainsack 2012) question the idea that people entertaining unhealthy behaviours *determine* their increased likelihood of higher healthcare needs. Even though agents can be regarded as subjecting themselves to additional health risks, lifestyle-related diseases aetiology can hardly be explained as *just* a matter of individual behaviour. Many factors concur in fact to the onset of patterns of risk (e.g. individual predispositions, environmental exposures, etc.), thus deflating the role of individual contribution to – and thus responsibility for – loss of health. Lifestyles are, in other words, only one of the causes contributing to health; hence, we should reject individual responsibility for unhealthy behaviours as a criterion for the allocation of resources in healthcare[16]. On the other hand, I also resorted to a different source of reasons for rejecting substantive claims of responsibility for health. According to this view (Brown 2013), appeals to responsibility for health are morally problematic because they conflate *causal* responsibility for disease aetiology with *moral* claims of responsible agency for unhealthy behaviours. Although it is impossible to deny that as individuals we have a fundamental

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[16] To reinforce this claim, solidarity scholars (Buyx and Prainsack 2012) also rightly point out that distributive matters in healthcare cannot be resolved by looking only at one source of normativity, i.e. the value of individual responsibilities for lifestyle-related diseases. Establishing an entitlement to the use of healthcare resources depends also on other founding values of our society at large, such as the commitment to help others epitomized by solidarity-based practices and institutions. It will be useful to bear this point in mind when reading the analysis of the following section of this chapter.

bearing upon our health, it is far from clear – as shown by the author – whether we are *free* in doing so, and consequently whether we should be held responsible for our actions. Brown's account (2013) questions the fundamental criterion on which responsibility-sensitive accounts of justice in healthcare are grounded. Namely, that lifestyle and health-related choices are a matter of personal control and free agency. By juxtaposing Pettit's theory of freedom (2001) to knowledge of the social determinants of health (Marmot and Wilkinson 2003, World Health Organization 2013), she dismisses the claim that individuals ought be considered free in making – and thus responsible for – health-related behaviours.

The upshot of this section is therefore that matters of responsibility for health demand to be addressed by taking into account a different and broader set of considerations in order to be granted legitimacy. By showing us how lifestyle-related illnesses are less a matter of personal control than we might assume, the three critiques I presented in this section recast agent's behaviour in terms of psychosocial factors, environmental cues and influences that undermine the importance of individual contribution as a normative anchor point for healthcare resources allocation. The evidence that antecedent social and environmental influences determine behaviour stands in direct contradiction with the presumption that people have the ability to make free choices with regard to lifestyles. And, consequently, it undercuts the moral legitimacy of claims of responsibility and accountability for unhealthy behaviours. As a result of the present analysis, the ethical legitimacy of normative claims of *individual* responsibility, liability and freedom for health depends from the scrutiny of the complex tapestry of social factors having a bearing upon individual agency.

In addition, what I showed so far opens up an important ethical matter to be addressed by proponents of EBRs. If, on the one hand, appeals to responsibility for health within these documents are comparable to the kinds of normative exercises entailed in the perspectives introduced above, it is doubtful that the new kinds of agencies and relationships envisaged by these documents are something desirable from an ethical point of view. If, on the other, supporters of EBRs are instead willing to side with critics of appeals to responsibility in healthcare, and to uphold claims of responsibility for health that are not subject to the criticisms outlined above, the key question they are confronted with becomes the following: in what respects an empowerment approach to responsibility for health can avoid the unwanted consequences that the accounts examined here are likely to bring about? To the provision of an answer to this question, I will now turn for the rest of this chapter.

The conditions of responsibility for health under the empowerment approach

The importance of attending to the broader social and environmental determinants of health is well captured in some of the empowerment approaches to health promotion that I have introduced in Chapter 1. To recap, while analysing these understandings of the concept I resorted to a distinction between two meanings of the term empowerment; one referring to the *state* of an individual within a certain community or social setting (i.e. the goal of empowerment), and the other pointing to the *process* (i.e. the practical strategies or means) that is likely to bring about an empowerment state (Tengland 2008). The key attribute of these approaches, I argued, is that the dimensions of 'empowerment as a state' and 'empowerment as a process' are intertwined, and constitute an understanding of human agency that revolves around two aspects of the notion of control over determinants of health-related quality of life. We seize control over our health, i.e. we reach a state of empowerment, only if we also exercise control over the social process that produces empowerment. This means that, on the one hand, abilities such as self-determination and control (sometimes referred to as power-to) with regard to health-related agency play here a pivotal role. Being in a *state* of empowerment means, generally speaking, being able to make relevant decisions with regard to health, as well as to have the opportunities to act upon them. Yet, on the other hand, this emphasis on capacity and opportunities has to be complemented with the idea that control pertains also to the generative *process* (e.g. political action for change, community-based advocacy for health, etc.) that enables individuals (e.g. clients, groups, or communities) to achieve an empowered state (sometimes referred to as lack of power-over)[17].

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[17] In Chapter 2 I have further specified this view by showing how attending to these procedural requirements of this notion of control constitutes the non-paternalistic element of empowerment.

Otherwise stated, these understandings of empowerment put a strong emphasis on a notion of agency in healthcare that is quite different from the one we encountered in the appeals to responsibility for health analysed above. Individual behaviour is framed, from these perspectives, as inextricably related to transformations at the interpersonal, community and institutional levels[18] (World Health Organization 1986, Wallerstein and Bernstein 1988, Laverack 2005, Tengland 2008, 2012). Freedom and responsibility for health cannot be thus conceived, starting from these approaches, as separated – and perhaps only affected – by the social context. Quite the contrary, the *state* of being empowered (i.e. being in control of health-related quality of life) stands in a relation of mutual dependence with the mastery of the politically and socially contextual *process* that is expected to produce the empowering outcome. From such perspectives, we are empowered insofar as we are in control (at least to a certain extent) of the broader social system of which we are part, and consequently of the social factors that affect our health.

Although underspecified in its substantive terms, this fundamental tenet of empowerment points to a distinct kind of normative appraisal of matters of responsibility for health. Rather than being concerned with the ways in which *individual* responsibility is affected or undermined by the social environment and the determinants of health, some empowerment scholars focus on what can be called an *ecological* model of responsibility for health (Minkler 1999). They rule out the distinction between an individual domain of responsibility (as the *locus* of ethical scrutiny for judgements of praise, blame, and accountability), and the social forces that may get in its way. Quite the contrary, ascribing substantive responsibility for health to citizens entails, from these perspectives, attending to the value of having actions depend on

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[18] On the broader scale of EBRs, the only example of such a view is represented by the WHO's conceptual framework proposed in the "Ottawa Charter for Health Promotion" (World Health Organization 1986). With its emphasis on the "usefulness and the challenges of an approach that truly balances concerns with individual and broader social responsibility for health" (Minkler 1999, 133), such document epitomizes a vision of health promotion as "a process of enabling people to increase control over, and to improve their health" (World Health Organization 1986). By doing so, the Ottawa Charter can be safely assumed to be a unique example of policy document attending to the empowering goals of synthesizing personal choice and social responsibility in health. Among the principles that can be said to underlie this vision of health promotion it is in fact possible to enumerate: acting on the determinants or causes of health, eliciting high-level public participation, and using a variety of approaches that go well beyond lifestyle education and include legislation, organizational change, and community development.

and reflect agency as *embedded* within a given social environment and background. This means that, from such empowerment approaches, only if some social conditions are met we are entitled to devolve responsibility for health-related behaviours to individuals.

The moral difference between the notions of responsibility analysed in the previous section and the *ecological* model just introduced, can be captured by a distinction between a 'choice view' of responsibility and its 'holistic' counterpart (Wolff and de-Shalit 2007). Although diverging in their normative stance on matters of responsibility for health, all of the approaches to social policy we encountered so far share in fact the view that one bears responsibility for an act insofar as this is the result of one's *choices*. Some of them provide a positive answer to the question "are lifestyles and behaviours the result of individual choice?", thus providing normative justification to claims of responsibility. The standard example of this view, provided by the luck egalitarian perspective (Segall 2009, Voigt 2013), claims for example that a person is substantively responsible for the health-related consequences of her behaviour because she chose, voluntarily, to bring them about. Some others provide instead a negative answer to the same question. They maintain, for instance, that claims of responsibility are not legitimate because social factors and determinants undermine the possibility that lifestyles are *actually* the result of choices (Brown 2013). These two views support, as we have seen, distinct normative stances on responsibility for health, and yet both share the assumption that individual choice is the fundamental criterion for allocating responsibility for health. On the former, responsibility is equated with *attributability* of choices, i.e. the recognition that individuals do determine their lifestyles, their increased risk to develop a disease, and consequently are responsible for its potential outcome. On the latter, instead, responsibility is *substantively* understood so as that, in order to legitimise normative claims of responsibility, lifestyle-related behaviours must be shown to be the result of an exercise of freedom on the side of the agent (Scanlon 1998). The fact that individuals choose to entertain risky behaviours does not suffice to ground ascriptions of responsibility.

The holistic notion of responsibility at the basis of the *ecological* model in empowerment has instead different moral roots. What matters for this approach is the context in which choices are taken rather than just their freedom and authenticity (in the sense of the 'choice view'). The normative exercise required by ecological responsibility is thus concerned with a different version of the question we encountered in the case of the 'choice view'. Here, what we should ask ourselves is whether "it is reasonable to expect someone to act one way rather than another?" (Wolff and de-Shalit 2007, 80). Meaning that substantive judgements of responsibility for health, under the aegis of empowerment, pertain not only to individual freedom of choice, but also to broader social and political *opportunities* (Wolff and de-Shalit 2007) to control one's health:

> In judging whether someone should be held responsible for the consequences of their actions we should take all the impacts – costs and benefits – of potential action and non-action into account. On the view developed here, someone has a genuine opportunity to do x only if doing x is reasonable for them, in the sense that the costs of doing so are reasonable for them to bear. The relevant costs are the impacts on other functionings, and what is reasonable depends on the context (Wolff and de-Shalit 2007, 80).

This holistic or ecological view of responsibility is evident, for instance, in some empowerment approaches to mental health (Chamberlin 2013), to chronic disease care (Feste and Anderson 1995), and health promotion (Segal 1998, Tengland 2007, Laverack 2005). Empowering patients is in fact recognised across these different contexts as having a number of qualities, which may help us better qualify what kind of opportunities are relevant for such notion of responsibility. The emphasis these scholars put on individual freedom – as the condition for responsibility – is epitomized by the use of formulas such as "having decision-making power" (Chamberlin 2013), or control over one's "desires and actions" (Tengland 2007), and largely depends on individual abilities to change things in their environment. This means that 'opportunities' are regarded within this literature as possibilities to make changes in one's social context that both affect – and complement – health-related ability and wellbeing (Tengland 2007). In particular, such a reading of opportunities (as contributing also to relevant health-related abilities) for gaining control over health includes (i) having access to relevant information and knowledge (Chamberlin 2013), (ii) having the competence required to act on such information (Segal 1998), (iii) having a range of options from which to make choices (Chamberlin 2013), (iv) feeling confident of being able to make a difference (Koelen and Lindström 2005), (v) encouraging group and community action through the identification of common values, needs and goals (Feste and Anderson 1995, Laverack 2005), (vi) having the adequate material and economic resources to make a change in one's own life with regard to health (Chamberlin 2013).

It will be now clearer to the reader how this understanding of freedom as a basis of responsibility within empowerment resonates with some developments and amendments to the so-called capability approach (Sen 1999, Nussbaum 2000, Wolff and de-Shalit 2007). The terms "freedom" and "control" at the basis of these two frameworks are in fact conceptually related. In so far as we understand freedom as *opportunity*, rather than merely 'choice', any positive change in freedom is also an increase in empowerment, since these opportunities often consist of increasing individual control over their lives and health (Tengland 2008). This means that both on the empowerment and the capability approach whether it is reasonable to hold someone responsible for her health will, in turn, depend on an analysis of many aspects of a person's life, including her socio-economic status as well as her general freedom to exercise control over their health. And yet, a major difference exists between these two approaches. As we have seen in the case of my analysis of paternalism (see *infra* Chapter 2), the moral reasoning underlying empowering strategies in health promotion is grounded also on a distinct and normatively binding view of the role of practitioners and healthcare policy-makers, which pertains to the limitation of authoritative interferences entailed in their daily practice. Underpinning the empowerment approach is in fact the belief that patient or client's decision-making power can be enhanced only through a process of constructive and collaborative cooperation, participation and respect (Laverack 2005, Tengland 2008), which should not be vested by expert authority.

This emphasis upon the limitation of professional power affirms therefore a view of freedom as opportunity – in the terms of empowerment – which goes beyond the one of capability thinking. Besides recognising the importance of individual and community development (the genuine political opportunities that capability scholars have in mind), the sovereignty of an empowered agent appears to be also a relational concept, meaning that it involves necessarily an active role of facilitation and support on the side of professionals and policy-makers. The opportunities for freedom (and consequently responsibility) are not exhausted, under the empowerment approach, by improving general levels of health, minimal functionings, and security of the community (Robeyns 2011). Rather, the constituency of such opportunities entails an obligation on the side of the healthcare system (broadly conceived) to support and assist the individuals to change on their own and to become more independent in pursuing their health plans (see *infra* Chapter 3). Only if this kind of freedom (Taylor and Hawley 2006) is achieved we obtain the conditions for responsibility under the *ecological* model of empowerment.

Conclusions: an empowerment-based approach to responsibility for health

Instead of seeing responsibility as liability for one's behaviours, the view I present here maintains that ascriptions of responsibility are conditional to a state of freedom (or power) over ourselves, which consists of the opportunities (i) to transform our behaviour (with the support of professionals), and (ii) to affirm our presence and influence in the social life to which we belong. By doing so, the present analysis is meant to show how questions of responsibility for health within EBRs can be resolved by drawing on a source of normativity, which is fundamentally different from the one largely dominating the debate in healthcare ethics. When making substantive judgements such as "A is responsible for the health-related consequence X" – from the empowerment perspective defended here – we do not ask ourselves if A's *choices* are free (Segall 2009, Voigt 2013) or not (Brown 2013) in producing the consequence X. Rather, we are bound to plunge into the social and political conditions and *opportunities* in which such choices are made, as well as on the social and political influences that shape individual lifestyle and behaviours. What is argued here is, in other words, that a number of complementary responsibilities exist also on the side of the healthcare system for individuals to be able to legitimately assume responsibility for their health. The empowerment way casts in fact professionals and healthcare policy-makers in the role of facilitator and demands a number of support mechanisms that may provide the opportunities to enhance citizens' freedom and, in the long run, their ability to acquire responsibility for their own health.

Furthermore, this empowerment-based notion of responsibility for health can provide an alternative to the view at the basis of the responsibilization critique, pointing to the difficulties of solving these matters by trading off individual merit and possible sanctions for health-related behaviours. In countering the trend towards the individualisation of social policy in healthcare (Shapiro 2012), the perspective hereby proposed requires approaching normative matters of liability and accountability in healthcare by pointing to the inherently collective nature of moral and legal responsibility for one's behaviour. In doing so, my main aim has been that of nurturing the more accurate and socially aware estimation of the value of taking responsibility for our actions, which critics of EBRs and appeals to responsibility in healthcare demand. The main advantage of such an empowerment perspective is that it refrains both from an overestimation of people's freedom of choice – and hence responsibility – with regard to health-related behaviours, and an underestimation of the potential benefits that devolutions of responsibility for health may yield for people's opportunities to pursue their vital goals[19] (Nordenfelt 1995). It is in fact simplistic, if not wrong, to conclude both that people should be held responsible for their health-related behaviours *under all conditions* (Segall

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[19] It might be argued that my substantive requirement of freedom to be held responsible for one's health stands in contrast with the relativism of Nordenfelt's account discussed in Chapter 3. According to this potential reading, claiming legitimate only those health-related choices that are responsible under the ecological model would clash with the idea that levels of health should be relative to individual preferences. I maintain this contrast not to hold for the following reason. Nordenfelt's theory implies neither that all the choices with regard to one's vital goals stand on a par, nor that it is not possible to identify some criteria to judge better or worse choices with regard to one's vital goals. Rather, his theory of health only points to the importance of taking up evaluations of health that are relative to one's beliefs, values and preferences (i.e. one's vital goals). It might well be the case, under his theory, that a person's vital goals are inauthentic, that her vital goals are determined in full freedom, or also that the person is unaware of her vital goals. What I am positing here tries to identify a substantive requirement for discriminating among all of these possible scenarios, without therefore impinging upon the idea that health is relative to one's preferences and vital goals.

2009, Voigt 2013), and that conditions of freedom for responsibility for health hardly obtain when it comes to disadvantaged groups of our society (Brown 2013). Quite the contrary, empowering responsibility for health can be regarded as fostering a process whereby individuals can, if they wish so, enhance their control over their lives, health and welfare. Whether or not such process can be regarded as ethically desirable depends very much on the context, on the domain in which responsibilities are devolved, and on a variety of normative considerations.

In this respect, my analysis goes along the same lines of the intuition encountered above, coming from the solidarity-based rebuttal of claims of responsibility in healthcare (Buyx and Prainsack 2012), that an ethical appreciation of these matters demands a focus which is much broader than questions of freedom of individual *choice*. Deciding whether access to healthcare, or costs for services, or merely their use, ought to be sensitive to individual responsibility and lifestyles is to ascertain whether the political circumstances of individuals favour the development and acquisition of the essential characteristics for responsibility. And, most importantly, it means also asking ourselves whether we – as a society – find reasonable and ethically desirable for people to bear the consequences of their behaviours. Moral responsibility (in the sense of the 'choice view' mentioned above) is only one among many considerations for judgements of responsibility for health (Wilkinson 1999), from the perspective here developed. Such judgements are a rather broader and contextual matter, which demands also interrogating ourselves on the social obligations of providing genuine opportunities for taking up responsibilities with regard to our health. The main outcome of this analysis is therefore that of potentially helping health educators to acknowledge the importance of working systematically on the various educational, organizational, administrative, and policy determinants that, if properly addressed, are likely to bring about the desired outcome of an empowered and responsible citizenship in healthcare. And for this reason, the next section of this thesis will focus on one possible way of cashing out this normative theorization of responsibility in planning and evaluating multilevel empowerment practice in healthcare.

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Chapter 5. How to assess the effectiveness of empowerment in EBRs?

Introduction

Besides its influence on the development of what I called EBRs, the empowerment approach has increasingly gained currency across a number of healthcare contexts (Christens 2013). From the commitments upheld by the policy and reform documents (Colombo et al. 2012), to the practical development of strategies for the management and prevention of diseases (Wallerstein 2006, Herbert et al. 2009), empowerment is by now considered a "cornerstone of health promotion practice and philosophy" (Woodall et al. 2012, 742). Already a cursory review of the *practice* of empowerment confirms that this paradigm has now become influential both at the individual and the public health level. Empowerment plays a major role for the development of care strategies in a number of contexts, such as cancer care (Mok 2001, Wilson 2008, Stang and Mittelmark 2010, Ryhänen et al. 2012), end of life care (Martin 1998), health community action (Minkler 1997), mental health (Chamberlin 1997), diabetes management (Anderson and Funnell 2005, Asimakopoulou 2010), and more recently e-Health (Lodewijk 2012). Empowering initiatives have been shown to lead to better health outcomes and disease management in a variety of chronic conditions (World Health Organization 2002), and are deemed particularly suitable to contexts in healthcare where the agency and leadership of the people involved is key to the success of the intervention (Wallerstein 2006).

Parallel to the proliferation of empowerment-based intervention in healthcare, a variety of methods for the evaluation of its effectiveness have been developed. Ranging from qualitative, to quantitative and mixed methods, research on the effectiveness of empowerment has been focusing on the development of different instruments for its assessment across various healthcare settings (Wallerstein 2006, Herbert et al. 2009, Hudon et al. 2010). This section of the thesis aims at investigating the theoretical underpinnings of all of these instruments, by identifying the challenges ahead for the development of standard and reliable measurements of the effectiveness of empowerment. In addition, the goal of this chapter is also to identify available instruments for the measurement of empowerment that best meet the distinctive ethics of the approach defended throughout this work.

In pursuing this goal, I will proceed as follows. First, I will reconstruct the existing controversy surrounding the variety of instruments that have been used for evaluating outcomes of empowerment (Wallerstein 2006, Herbert et al. 2009, Hudon et al. 2010). In particular, I will describe three recognizable pathways of research on the instruments for measuring of empowerment (i.e. instruments for psychological empowerment, instruments for health-related outcomes of empowerment, instruments for community-based empowerment), and discuss their methodological strengths and limitations. What I will show is that two main reasons are at the basis of the dispute regarding how to best measure empowerment. First, this range of instruments grapples with the consequences of the *multi-level* nature of the empowerment conceptual construct. Since empowerment can be understood, operationalized and implemented differently – depending on whether it is expected to lead to individual enablement, health-related outcomes, and community action for policy change – very different measurements may be required to capture indicators of its success across various healthcare settings. Second, the lack of definitional precision of empowerment is reflected, in a robust disagreement about how we should conceive its *effectiveness*, and the measurement of its outcomes.

In an attempt to position my analysis within such dispute, the concluding section of this chapter will focus instead on whether my conceptual approach to empowerment privileges some methods to assess its outcomes. Accordingly, I start by summarizing the main normative tenets of empowerment presented in this work. I argue that the shift prompted by EBRs from *control* over life and health (Green and Tones 2010) to *responsibility* for health has at least one major implication for the design of empowerment interventions and their measurements. Methods for the evaluation of empowerment should privilege, under my interpretation, a multi-level assessment of its effects. From "active processes of change and transformation" (Rifkin 2003, 169), to psychological and health related outcomes, the normative foundations of empowerment I identify demand methods that integrate all of these dimensions in the assessment of its outcomes (Woodall et al. 2012). This recognition, I conclude, calls for abandoning the mutually exclusive approaches to the design of empowerment measurements at the basis of the three recognizable pathways of research discussed here.

How to measure the effectiveness of empowerment?

To evaluate the effectiveness of empowerment is to do (i) an analysis of how a given definition of the concept is operationalized, and (ii) to estimate the reliability of the instruments we use to determine its successful implementation. On the one hand, the way we understand empowerment plays in fact a major role as to the variables, indicators and outcomes (Herbert et al. 2009) that we want to observe in operationalizing the concept. Otherwise stated, conceptual approaches to the *implementation* of empowerment are inseparable from the methodological considerations for their *assessment*. Whether we describe empowerment as the possibility to control one's life and health (Rappaport 1987), or whether we understand it as the process of bringing about health-related social change – in terms of "skills, resources, opportunities and authority" (Rodwell 1996, 309) – will no doubt discriminate among empirical strategies for determining the success of the intervention. On the other, evaluating the effectiveness of empowerment demands that questions of generalizability and reliability of the data obtained are addressed. Apart from the variability in the definitions of concept, one major problem in measuring empowering outcomes lies therefore in the fact that empowerment is commonly described as a contextual and participatory process. Processes of empowerment tend to be tailored for use in a specific context or population: to what extent should we then expect them to produce generalizable knowledge for different healthcare settings?

The recognition of these difficulties in the operationalization and assessment of empowerment has led some scholars to conclude that the nature of the approach calls for refraining from lusts of reproducibility and generalizability (Rodwell 1996, Gibson 1991).

'Universal measurements' (Wallerstein 2006) of empowerment are, under this interpretation, not only insufficient, but also undesirable because they fail to take up the local culture, language and context in the design of practical strategies. According to this view, empowerment is a support process, a partnership between professionals and participants that can hardly be reconciled with a static view of the concept to be applied across different contexts. An appropriate means of generating knowledge on the success of empowerment is rather that of using "a qualitative approach such as ethnographic or phenomenological research" (Rodwell 1996, 310)[20]. Some other scholars have instead tried to overcome this issue by demanding the construct of empowerment to gain "conceptual maturity" (Herbert et al. 2009, 126). The main reason for the difficulties in developing general instruments to measure empowerment, this line of reasoning goes, lies in the lack of clarity as to the theoretical underpinnings of the approach. Bringing the concept to its conceptual maturity can render the characteristics of the approach well-defined, regardless of the context of its application, and hence provide us with specific boundaries as to its conditions, variables and outcomes that is worth measuring. This view calls for the development of measurements, based on common attributes of the construct of empowerment, to be employed and compared across different contexts.

Despite the reluctance of some scholars to provide empowerment with conceptual and methodological strictness, growing evidence supports the view that standardization of (the concept of) empowerment across different contexts could indeed benefit the reliability and validity of the data obtained. In particular, studies assessing the effectiveness of empowerment have followed three major research pathways. Instruments for measuring

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[20] Phenomenological research is a common design in sociology, philosophy and psychology. Under this approach, the researcher describes the lively experiences of individuals dealing with a phenomenon, by resorting to their description and perception of such experiences. The researcher's task is typically to identify common traits among the experiences of several individuals through interviews and observations. Phenomenological research is characterized as ethnography when the researcher studies a certain phenomenon in terms of "behaviours, language, and actions of an intact cultural group in a natural setting over a prolonged period of time" (Creswell 2014, 14). Within empowerment studies, some authors have privileged phenomenological research because of its flexibility (Laverack 2005). By resorting to qualitative interviews and observational data, the researcher leaves open the possibility that concepts and variables emerge from the respondent's perspective, thus accommodating the ideas of participation and capacity-building at the basis of these interpretations of empowerment.

empowerment have been developed for (i) psychological/enabling outcomes (Hudon 2010), (ii) enabling and health-related outcomes (Herbert et al. 2009), and (iii) community-based outcomes (Laverack 2005, Wallerstein 2006). As we will see, trends towards the establishment of general and context-independent measurements of empowerment are however at different stages of development. Measurements of empowerment in the case of psychological and health-related outcomes are in fact much more refined and generalizable than those used in community-based health programs. The attention to local context and health issues at the basis of the latter can in fact hardly be reconciled with the search for general instruments for the assessment of its effectiveness. To a discussion of each of these pathways, and their methodological foundations, I will now turn for the rest of this section.

Pathway 1: Instruments for psychological empowerment

The first pathway we take into consideration focuses on measurements of the psychological effects brought about by empowerment interventions. A controversy exists, however, as to what extent psychological empowerment should embrace an emphasis on skills, knowledge and awareness at the individual level. Some authors (Zimmerman and Rappaport 1988, Christens 2013) have argued that individually oriented conceptions of empowerment are limited because they neglect the importance of contextual considerations and community-oriented actions. According to this line of reasoning, privileging the micro level (i.e. individual level) at the expenses of the meso level (i.e. community level) fails to take up the Freirian ideas of liberation and collective action at the roots of the approach (Freire 1972). Otherwise stated, there is a risk entailed in the focus on individuals within the framework of empowerment: the dilution of this approach into an individualistic enterprise, rather than "a discipline that focuses on addressing social justice and wider power structures through social and structural change" (Woodall et al. 2012, 743). Differently from this view, other authors have instead contended that an important component of empowerment lies in its *enabling* aspects, such as improved individual decision-making capacity, and ability to control health and life (Hudon et al. 2010). Typically, these scholars consider feelings of empowerment as the main goal of the approach (Faulkner 2001b), and claim that psychological outcomes of empowerment should be distinguished from their link to health improvements (see Pathway 2) and/or the production of social change (see Pathway 3). Regardless of whether empowerment results in improved health or effective social agency, these authors argue, the element of individual enablement has to be considered as a dimension of empowerment valuable in itself (Wallerstein 2006).

Interpreting psychological empowerment in this sense means therefore devising an approach that focuses on individual perception of the situation, as separated from outcomes at the interpersonal/community level, as well as developing adequate instruments that may capture such effects. In following this line of reasoning, Hudon and colleagues (2010) provide us with a systematic review of the available instruments to assess the *enabling* aspects of empowerment in clinical practice. Instruments included in this study were selected from databases of academic literature only if they satisfied the three following criteria: 1) development and/or validation of an instrument; 2) evaluation of enablement defined as "an intervention by which the health care provider recognizes, promotes and enhances patients' abilities to control their health and their lives" (Hudon et al. 2010, 1302); 3) quantitative results following administration of the instruments. Among the 3800 citations identified by this bibliometrical analysis, only 4 articles, coming from two different research groups, were retained on the basis of the criteria stated above (see Faulkner 2001a, 2001b, Kettunen et al. 2001, Kettunen et al. 2006 in Hudon et al. 2010). All of these articles make use of two different constructs and instruments that have been respectively developed by the same groups of authors: the Patient Empowerment Scale (PES), and the Empowerment Speech Practices Scale (ESPS). Both of them can be defined Mixed Methods Research designs (Creswell 2014), as they both involve collecting quantitative and qualitative data and integrating them[21]. Let us now turn to an analysis of the methodological foundations of both these psychometrics of empowerment.

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[21] Mixed methods research is a relatively new approach in the humanistic sciences (Creswell 2014). It is deemed particularly useful because of its capacity of drawing both from qualitative and quantitative data. By doing so,

The PES (Faulkner 2001a, 2001b) builds upon the assumption that empowerment processes are a matter of interaction between a professional and a patient. The key aim of empowerment, according to this interpretation, is maximising the independence of patients through *actions* undertaken by healthcare professionals, such as nurses. Starting from this assumption, the PES establishes a model of empowerment based on prototypical acts associated to empowering and disempowering behaviours, and consequently proposes a methodology for its evaluation. By identifying actions that are beneficial or detrimental for patient's independence, "empowerment and disempowerment are transformed from invisible concepts to visible variables" (Faulkner 2001b, 938) that can be observed and quantified. The construction of such quantitative measure of empowerment follows what can be called an *Exploratory Sequential Mixed Method* (Creswell 2014). This approach is a particular design in mixed methods that begins with a qualitative phase followed by a quantitative stage. The aim of such strategy is to develop measurements with a specific sample of populations, and to determine whether data collected from a few individuals (qualitative stage) can be generalized to a larger sample of the population (quantitative stage). For this reason, *Exploratory Sequential Mixed Methods* typically involve a three-phase procedure (Creswell 2014). The researcher (i) collects focus group/interview data and analyses the results, (ii) devises an instrument by building on the results of the first phase, and (iii) finally administers the instrument to a sample of the population. According to Faulkner (2001b), the main components of empowerment measured by the PES consist of promoting (i) patient independence, (ii) awareness of patient needs, and (iii) information exchange. As to disempowerment instead, the primary components captured by the PES: (i) impeding patient collaboration in care planning, (ii) domination, (iii) indifference to patient needs.

As stated above, the second instrument for measuring psychological empowerment identified by Hudon and colleagues (2010) is the ESPS (Kettunen et al. 2006). The purpose of

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mixed methods are deemed to minimize the limitations of both qualitative and quantitative approaches. On a practical level, mixed methods can provide a better explanation of quantitative results with a qualitative follow-up (e.g. enriching experimental results by incorporating the perspective of participants), and developing better quantitative instruments by first collecting and interpreting qualitative data. The latter interpretation of mixed methods will be problematized in the present analysis of measurements for psychological empowerment.

the ESPS is to assess the empowerment of counselling practices in nursing as a means to strengthen professional training and improve the quality of services. Differently from the PES, the ESPS starts from the assumption that the enabling aspects of empowerment should not be assessed through personal feelings of control, ability and independence on the side of professionals and/or patients. Rather, empowerment obtains within what the authors call *dyadic counselling* (Kettunen et al. 2006, 160). Empowerment, according to this view, obtains in the making of a cooperative relationship that improves individual ability for decision-making, and feelings of control over the healthcare process. It is therefore within the counselling encounter between a patient and a nurse that empowering outcomes can be achieved, and consequently measured. With this in mind, the authors developed the ESPS in a process that also falls under the category of *Exploratory Sequential Mixed Methods* (Creswell 2014). Six main categories of empowering communication acts can be investigated through the use of the ESPS: 1) "setting expectations for discussion, 2) offering individualized information and advice, 3) facilitating reflection, 4) constructing a positive atmosphere, 5) respecting and bringing up the patient's competence concerning health and 6) the patient's assertiveness" (Kettunen 2006, 161). The dimensions of empowerment that scored best in the experimental setting of this study were 4) and 1), while the rest of them called for further improvement of the interaction within the counselling encounter (Kettunen 2006, 163).

No doubt, both the PES and the ESPS build upon the strengths of *Exploratory Sequential Mixed Methods* (Creswell 2014). Typically, this research design is particularly useful to explore concepts or phenomena in lack of an adequate instrument for their measure. The qualitative phase at the beginning of this design (the so-called 'exploratory phase') enables the resulting instrument to capture previously unknown themes, codes and actions that are relevant to the understanding of the phenomenon under study. Thanks to this design, the PES has the merit of having established, for the first time, a robust link between a given list of prototypical acts and (dis)empowering feelings of (in)dependence in patients. Similarly, the ESPS represents a first systematic attempt of structured analysis of counselling encounters, and makes some critical factors of empowerment visible and measurable. With the aid of both these tools, professionals can evaluate their practices and critically determine possibilities of improvements of the services provided. However, it is also worth mentioning that the generalizability of data under the *Exploratory Sequential Mixed Method* could be limited. The richness of the qualitative data obtained through the exploratory phase is a great advantage in developing instruments that fit the sample *under study*. One consequence of adopting this design is, in other words, that the resulting instruments are less appropriate when considering a different sample of patients.

Although the PES and the ESPS may be considered valid psychometric instruments, their reliability may be thus limited in healthcare contexts different from the one in which they were developed. The PES should be regarded as indicating no more than the extent to which a particular hospital unit is empowering or not (in light of a list of prototypical empowering acts); the ESPS, instead, as a measure for the empowering effects of a specific set of counselling interactions in hospital care. Feelings associated to empowerment may be different across different healthcare settings, and can be hardly captured by any of these instruments. This limitation embedded in *Exploratory Sequential Mixed* designs must be taken into account when dealing with this kind of approaches to the assessment of psychological empowerment, and calls for a further development and improvement of context-independent measurements (Hudon et al. 2010).

Pathway 2: Assessing health-related outcomes of empowerment

Within the second pathway, health improvements and health-related outcomes are deemed to be one of the relevant results of the empowerment intervention. Apart from generating feelings of enablement, this line of reasoning goes, empowerment should be evaluated also as to its effect at the level of health-related behaviours. It follows from such recognition that measurements of the effectiveness of empowerment should not limit themselves to its psychological and enabling aspects. Rather, the evaluation of empowerment should include also other quantifiable outcomes, such as disease or risk factors-related objectives.

The ways in which empowerment can and should bring about health improvements is, however, also a matter of disagreement. According to Wallerstein (2006), health-related outcomes of empowerment can follow two different approaches. On the one hand, empowerment has been shown to improve individual decision-making capacity, disease complication management and health-related behaviours. In this respect, empowerment can be considered to *directly* bring about health-related outcomes, such as a change in the lifestyle, or the adoption of a given treatment strategy. On the other, different approaches have focused on strengthened support groups, caregiver empowerment, and enhanced access to health services (regardless of a focus on a given lifestyle-related change, or treatment adoption), that are deemed to produce *indirect* health benefits for the people involved. No consensus exists as to whether this divide should be the driving force behind measurements of the link between empowerment and health improvements. As argued by Tones (1998b), both of these elements should be considered two inseparable components of a broader commitment to health-related outcomes in the discourse of empowerment. According to the author, group and community "participation is not only ideologically but also practically a *sine qua non* of effective healthy programs" (Tones 1998b, 185). From his perspective, healthy choices are not to be addressed by education for individual empowerment *or* social and organizational change. Quite the contrary, the promotion of people's health is a salutogenetic[22] process that can only be achieved by addressing the *reciprocal* relationship between individuals and their environment. Whether or not empowerment can lead to better health levels, this line of reasoning goes, depends on the extent to which individuals are directly "*self-empowered"*, as well as on the degree of their participation to active community-action (Tones 1998b) from which health benefits are indirectly achieved.

To the best of my knowledge no systematic approach exists at collecting evidence of empowerment and indirect health outcomes across different contexts. Although there is a

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[22] Such a relationship between empowerment and health builds upon the theoretical construct of *salutogenesis* proposed by Antonovsky (1984). Based on the idea of *sense of coherence*, the notion of 'salutogenesis' represents an orientation of individuals, which is expressed thanks to "a pervasive, enduring though dynamic feeling of confidence that one's internal and external environments are predictable and that there is a high probability that things will work out as well as can reasonably be expected" (Antonovsky, 1984, 123).

widespread consensus on the effectiveness of empowerment in addressing health-related community issues, the field appears to be still in search of such tool (Tones 1998b, Rifkin 2003, Wallerstein 2006). As we will see in the analysis of community-based assessment of empowerment (i.e. Pathway 3), this is mainly due to the difficulties of creating an instrument for community empowerment that is "practical, valid, and reliable", and at the same time capable of moving across "local situations that are influenced by culture, history, and current social, political and economic factors" (Rifkin 2003, 177).

On the contrary, measurements can be found when it comes to health-related empowerment at the individual and family level. However, little can be said about their validity and reliability. The methodological limitations of these instruments are the main subject of a systematic review of the available tools published by Herbert and colleagues (2009). The aim of the authors was to identify measurements of health-related empowerment matching some basic methodological standards. Instruments included in this study were selected from databases of academic literature only if they satisfied the two following criteria: 1) an English abstract reporting measurements of health-related empowerment in individuals or families; 2) a methodological discussion of (a) the theoretical basis of the questionnaire, (b) the number of items in the questionnaire, (c) the population studied, (d) data on reliability of the instrument, and (e) data on validity of the instrument. Among the total 8269 abstracts reviewed by this study, only one instrument was found to fully satisfy the two criteria stated above[23], and thus classified as having good "evidence of reliability and validity" (Herbert et al. 2009, 124). Such instrument, the Parent Empowerment Survey (Trivette et al. 1996, in Herbert et al. 2009),

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[23] Herbert and colleagues (2009) found also that four further instruments produced moderate levels evidence (Koren et al. 1992, Man 1998, Akey et al 2000, Man 2001, in Herbert et al. 2009). I will not delve into the details of all these different measurements of health-related outcomes of empowerment. Suffice to say, for the purpose of this work, that common elements exist between the five questionnaires rated as having good (one) or moderate (four) evidence (depending on variability in levels of reliability and validity). All of them are based on similar empowerment constructs that are associated to health-related behaviours and outcomes: the Family Empowerment Questionnaire (Man, 1998) stems from an empowerment model understood as "knowledge, skill, and support at the personal, familial, and societal levels". Likewise, the Empowerment Questionnaire (Man, 2001) is based on "an empowerment model consisting of information, skills, support, and hope". The Family Empowerment Scale (Koren et al., 1992) builds upon "a two dimensional framework of empowerment consisting of the level of empowerment and the way empowerment is expressed through attitudes, knowledge, and behaviours". Finally, the construct at the basis of the Psychological Empowerment Scale (Akey et al., 2000) is "psychological empowerment including intrapersonal, interactional, and behavioural aspects" (Herbert et al. 2009, 124).

measures the sense of control of parents over life events, and builds upon a conceptualization of empowerment that consists of "six dimensions including philosophy, paradigm, process, partnership, performance, and perception" (Herbert et al. 2009, 124). At the basis of this questionnaire lies the idea that empowerment spans across two distinct dimensions (Herbert et al. 2009). First, the *intrapersonal* dimension, where we can recognize factors related to what we called 'psychological empowerment' (i.e. knowledge, skills, attitudes, philosophy and perception). Second, the *behavioural* dimension that relates to health-related performance of the individuals involved in the intervention. Let us now turn to a methodological analysis of this kind of instrument.

There are a number of reasons that can explain the modest strictness of most instruments measuring health-related empowerment, with the only exception of the Parent Empowerment Survey (Trivette et al. 1996). First, one problem lies in the definitional vagueness of the approach (Herbert et al. 2009). As mentioned above, a clear conceptualization of empowerment is a crucial component for the construction of a good instrument. Whether we establish clearly what are the relevant determinants of empowerment (and consequently its relevant measurable factors) has in fact an impact over the operationalization of the concept in the form of a questionnaire. One limitation of most of these instruments is, therefore, the poor congruence between the theoretical and operational definitions of empowerment they adopt (i.e. their construct validity). Second, constructing valid measurements of empowerment is no easy task due to the context-specificity to which the approach has been confined so far. As we already noted in the case of psychological empowerment, empowerment theorists and researchers tend to privilege local interventions and research approaches. In general, this attention to context stems from the declared commitment of empowerment to the promotion of a bottom-up approach to health programs and interventions. Overall, designs of empowerment programs are deemed to be concerned with "empowering" indicators (e.g. enabling/psychological factors, and disease management objectives) based on local culture and context (Labonte and Laverack 2000). Such contextual indicators are seldom characterized as general attributes of the construct, and are almost unanimously considered a distinctive feature of the "radical" approach at the grassroots of empowerment (Tengland 2008, Wooddall et al. 2012). Yet, championing the "radicalism" of the approach can come at the expenses of validity and reliability of instruments for empowerment across different healthcare contexts.

Despite the growing interest in comparing and evaluating measurements of health-related empowerment (Herbert et al. 2009), it appears that methodological issues are still in need to be addressed also within the second pathway of instrument development just discussed. Very much like in the case of psychological empowerment, a trend towards standardized measurements can be observed in the literature. In this respect, the study by Herbert and colleagues (2009) represents a pivotal attempt at systematizing instruments for health-related empowerment, and provides good evidence of the need for their refinement. A consistent effort towards methodological considerations of reliability and validity of instruments is however required, before making context-independent measurements available to the scientific community.

Pathway 3: Instruments for community-based empowerment

We turn now to the analysis of how empowerment as a means might be expected to instigate change at the community level, and to the possible strategies for the measurement of its outcomes. As we noted previously, a central tenet of empowerment – for some of its proponents – is the importance of community participation in health promotion. Community-based strategies are deemed to be a fundamental aspect of empowerment not only because they are an "integral part of the ethics" of the approach, but also because changes are unlikely "to occur or to be sustained" (Tones 1998b, 195) if citizens are not involved in relevant political decision-making processes. Such a potential of empowerment to produce health *and* societal outcomes is confirmed by an influential review on the effectiveness of empowerment published by the European Regional Office of the World Health Organization (Wallerstein 2006). According to the author, citizen participation is in fact critical in "reducing dependency on health professionals, ensuring cultural and local sensitivity of programs, facilitating capacity and sustainability of change efforts" (Wallerstein 2006, 8). Differently from psychological and health-related empowerment, community change through empowerment operates at the so-called *meso*-level of action (Tones 1998b). Namely, the emphasis of this approach falls on the organizational level integrating the micro-level of individual education for health and the macro-level of participatory initiatives for policy change. Community engagement within empowerment is thus understood as a "complex and iterative process" of individual and community education, "which can change, grow or diminish based on the unfolding of power relations and the historical/social context of the project" (Wallerstein 2006, 8). The purpose of community empowerment is, in other words, that of challenging cultural and local power structures through 'critical-consciousness raising' (Freire 1972), addressing inequalities in health and healthcare provision (Rosenthal 1983), "advocacy and leadership training, organizational development, and transfer of power to participants" (Wallerstein 2006, 9).

These characteristics of community empowerment make it an approach that is hardly controllable or predictable – and hence measurable – in its outcomes. For this reason, community levels projects have rarely committed themselves to the development of standard measurements of their outcomes (Laverack 2005). Rather, instruments for community empowerment have more often resorted to social inquiry techniques like qualitative interviews, and observational methods. In particular, two main types of interviews have been used under this approach (Laverack 2005). *Unstructured* interviews, which cover only a few issues and are generally directed at eliciting the view of participants; and *semi-structured* interviews, which are conducted on the basis of a loose structure made of open-ended questions (Creswell 2014). Choosing between the two depends very much on the aims of the empowerment intervention under study. Unstructured interviews have in fact the advantage of letting participant's opinion direct and structure the encounter with the professional, while semi-structured interviews represent an attempt at trading off the interest of the researcher/professional in exploring a particular issue, and the expression of the interviewee's view.

Both kinds of interviews are generally aimed at evaluating the accomplishment of the agenda of an empowerment intervention. Whether the researcher thinks that her role is primarily the collection of views from the participants, unstructured interviews may be however the best tool for 'taking a back seat' (Laverack 2005) and letting people set their own community agenda for empowerment. By contrast, semi-structured interviews emphasize the role of facilitator that the professional can play in determining the most relevant actions to be undertaken (Charmaz 2006). Parallel to the use of one-to-one interviews, a convenient way to reach this result is represented by group-interviews, or *focus groups* that guarantee the simultaneous collection of data from several participants. By gathering groups of stakeholders around the task of identifying and discussing health-related issues, researchers can gain depth and comprehension of the main disempowering factors in the life of a community. Detailed observation of behaviours and conversation among participant can in fact reveal and promote in many ways the awareness of social causes related to health-issues in the community. First, people coming together to discuss a topic will "inspire" each other, and can come up with "facts" about their community that they might not come up with in one to one interactions. Second, there is a dynamic in the group that can be studied (e.g. gender-based and other power relations), which might be important in a small community, since it might have disempowering and health-related consequences alike (Tengland, *personal communication*).

As noted above, community empowerment is not limited, however, to the collection of data about members' perception and attitudes towards health. Such in-depth analysis of dynamics and meanings in a community is no more than what could be called the first 'exploratory stage' of community empowerment. The main aim of these projects is a rather different one: working as catalysts in stimulating local health-related *action for change* (Tones 1998b). With regard to the 'action stage' of community empowerment, it should be noted that a robust disagreement exists as to how to characterise it, and consequently measure it. Some authors interpret "action" as disrupting social structures that run against health (Fals-Borda 1987, Minkler 2000). According to this interpretation no community empowerment *really* takes place until a change in the social arrangements and determinants of health is achieved.

Typically, this entails the production of tangible and positive policy changes, in terms of institutional commitments or health programs that should be then included in the indicators for the measurement of the intervention. Some different scholars have instead put a strong emphasis on critical consciousness to be raised through educational programmes (Freire 1972, Tones 1998a). Empowerment obtains, under this interpretation, when educational programs put individuals and communities in the position of dealing better with consequences and determinants of the health-related issues that they themselves have identified. One declared strength of this approach is that of addressing an important ethical dilemma of health promotion: promoting the health of the public, while at the same time respecting individual freedom. No special commitment to the prevention or treatment of diseases is in fact entailed in the emphasis on education for community empowerment. From this perspective, empowerment has a special moral standing because it *educates* everyone to make health-related decisions in freedom, "including the freedom to adopt unhealthy lifestyle" (Tones 1998a, 57). Consequently, measuring this kind of 'action for change' within empowerment means assessing individual and community awareness, and knowledge resulting from the educational programs undertaken. Finally, other authors have championed community empowerment as to its capacity of reducing health inequalities (Wallerstein 2006) through the removal of psychosocial, cultural, or institutional barriers to health in marginalised groups of society. Empowerment strategies are, according to this view, effective insofar as they challenge "control and social injustice through political, social and psychological processes" (Wallerstein 2006, 18) that enable oppressed people to develop their social capital.

I will not delve into the details of each of these different understandings of what I called the 'action stage' of community empowerment. For the sake of this analysis, it is however important to keep in mind that the diversity among these accounts of the 'action stage' is another major contributor to the present lack of standard tools for the measurements of community-based interventions. Evaluating the effectiveness of healthy community empowerment programs rests in fact upon a wide range of social, political and economic factors that impair the identification of standard indicators for their success.

The ethics of empowerment in EBRs: suggestions for a methodological framework

The three research *Pathways* currently dominating the practice of empowerment point to a number of deployable methodologies to quantify relevant empowering outcomes. Yet, no methodology exists which can demand empowerment scholars a unilateral commitment to one kind of research model or method. In general, it could be argued that instruments for the evaluation of the effectiveness of empowerment consistently show the *multi-level* construction of the approach (Wallerstein 2006). Empowerment is a viable health strategy that spans across psychological, health-related and community levels of intervention and thus demands different strategies for its evaluation. At these three distinct levels, it is also clear that some studies have at least tried to develop these instruments and expand their viability beyond the local context. From personal perception or self-efficacy, to collective and community action, indicators of the success of an empowerment intervention are however still determined locally. Nevertheless, many examples of a *trend* towards the identification of context-independent measurements can be identified in the literature on the methodological foundations of empowerment. The key message of the previous analysis is therefore that measuring the success of empowerment strategies still depends very much on the conceptual construct we adopt. Methodological approaches to measurements of empowerment privilege in fact either the psychological, or the health-related, or the community-based goals of a given intervention.

What remains to be shown at this stage of my thesis is however the kind of measurement of empowerment that is more consonant with the perspective defended throughout this work. To address this issue it may be worth reiterating briefly the main conclusions of Part 1. Chapter 1 started from a historical analysis of what I called EBRs in (relevant) recent policy-making literature (see *infra* Chapter 1). Here, I noted how a "new wave" of empowerment in healthcare policy and reforms has produced a shift in the substantive foundations of empowerment. The emancipatory discourse of *control* and liberation from social oppression traditionally associated to the concept (Freire 1972, Tengland 2008) has recently become a discourse allegedly aimed at a renegotiation of power relationships in healthcare through devolution of responsibility for health. Moving on from this descriptive analysis, I then argued that this paradigm-shift in the *bundle* of values at the basis of empowerment is likely to generate some ethical controversies. In particular, I discussed issues related to *paternalism* in EBRs (see *infra* Chapter 2), to what I called the 'charge of *healthism*' (see *infra* Chapter 3), and finally to the potential unwanted consequences of different evaluations of *responsibility* within this context (see *infra* Chapter 4).

Briefly put, a number of distinctive ethical aspects of empowerment emerge from my analysis. First of all, I argue that the sustainability of EBRs requires professionals to refrain from paternalistic *attitudes* towards their clients (Dworkin 2010, Hershey 1985). More specifically, I show that an anti-paternalistic empowerment process demands professionals and healthcare policy-makers to act as facilitators (rather than leaders) (Tengland 2008), by (i) refraining from *attitudes* discounting patient perspective, and (ii) by putting in place a number of support mechanisms that may provide the opportunities to enhance citizens' freedom and, in the long run, their ability to acquire responsibility for their own health. This conclusion draws both on considerations of healthcare client's autonomy and the need to keep up with the anti-paternalistic promise of the discourse of empowerment in contemporary medicine (see *infra* Chapter 2). Secondly, I also show how the ways in which we evaluate the concept of health is not neutral with respect to an ethical appraisal of EBRs. Rather than understanding health as an objective standard to which citizens are "empowered" to conform (Veitch 2010), I argue that the empowered responsibility entailed in EBRs requires privileging individual self-determination in choosing what levels of health are relevant to the achievement of one's own vital goals (see *infra* Chapter 3) (Nordenfelt 1993, 1995, 2001, 2012, *forthcoming*). This means that the normative appreciation of empowerment I defend, calls for opening up opportunities for citizens to formulate their own relevant health goals. But also, if we combine this conclusion with the one from Chapter 2, that such a decision should not be subjected to paternalistic interferences by professional expertise.

This conclusion raises however another important question regarding the legitimacy of EBRs. Namely, it points to the question of whether *all* kinds of choices with regard to one's health and vital goals can be legitimately considered to be responsible ones (Wilkinson 1999, Feiring 2008, Voigt 2013). As to this matter, I show that we have convincing arguments (Buyx and Prainsack 2012, Albertsen 2013, Brown 2013) against the thesis that it is morally legitimate to interpret the shift towards responsibility in EBRs as liability and accountability for one's *choices*. Rather, I argue that an empowerment-based perspective on these matters points to the necessity of a full appreciation of individual capacity *together* with its broader social environment. For this reason, I develop an *ecological* model of responsibility for health (Minkler 1999), which points to freedom as opportunity, rather than freedom of choice, as the relevant condition for an empowerment-based notion of responsibility. Instead of seeing responsibility as liability for one's behaviours, the view I present maintains that ascriptions of responsibility are conditional to a state of freedom (or power) over ourselves, which consists of the opportunities (i) to transform our behaviour with the non-paternalistic support of professionals (see *infra* Chapter 2), and (ii) to affirm our presence and influence in the social life to which we belong.

It is worth noting here how this normative theorization of empowerment could represent the basis for the development of specific methodological approaches to its evaluation, which span across all of the three separate *Pathways* I identified in the literature. The focus on non-paternalistic attitudes of professionals (Dworkin 2010, Hershey 1985) has in fact the implication of demanding an evaluation of (my account of) empowerment, which is able to take up the enabling outcomes of the approach (i.e. those relevant to Pathway 1). Very much like in the case of the PES (Faulkner 2001a, 2001b) or the ESPS (Kettunen et al. 2006) analysed above, my approach to empowerment points to psychological enablement of healthcare clients (which obtains through non-paternalistic professional support[24]) as a

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[24] The emphasis upon non-paternalistic professional support entailed by my approach to empowerment should not be confused with existing notions of non-directiveness in genetic counselling and shared decision-making (Petersen 1999, Elwyn et al. 2000). While paternalistic actions – under my understanding – pertain to the attitude of the professional towards the client (see *infra* Chapter 2), directiveness is instead concerned with the content of

fundamental component of its effectiveness. In particular, the emphasis the ESPS puts on the importance to target the cooperative relationship between a professional and a patient, as the relevant locus where empowerment occurs (Kettunen et al. 2006, 160), goes in the same direction of the requirements to (i) refrain from attitudes discounting patient perspective, and (ii) to support citizens' enhancement of freedom I defend in Chapter 2.

At the same time, health-related outcomes of empowerment (i.e. those concerning Pathway 2) are of no less importance in the conceptual framework I propose. Even though my focus on behavioural outcomes of empowerment has to do with the identification of one's own relevant conception of health (Nordenfelt 1993, 1995, 2001, 2012, *forthcoming*) – rather than the achievement of disease-related objectives – a second relevant component of my normative analysis of empowerment points to the importance of producing (and hence measuring) health-related outcomes. In particular, the approach to health I defended from moral grounds points to the need to evaluate the capacity of empowerment to produce *indirect* health benefits for the people involved (Wallerstein 2006, Tones 1998b). By providing support to individuals in the identification of their *vital goals* (Nordenfelt 1993, 1995, 2001, 2012, *forthcoming*), and the consequent levels of health, my account of empowerment requires an appreciation of how the *empowered* individual effectively takes up a commitment to (what she deems to be) health improvements.

Finally, the ecological model of responsibility I defend for the ethical sustainability of EBRs suggests that an important dimension of empowerment lies also in one's freedom of opportunity to affect the broader social system of which we are part, and consequently the social factors influencing our health. I further specified this *ecological* model of responsibility (Minkler 1999) as the opportunity to (i) have access to relevant information and knowledge

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the communication process underlying medical encounters. As argued by Elwyn and colleagues, (non) directiveness means in fact (not) guiding the client "towards any particular decision (for example, to test or not to test, to terminate a pregnancy or to continue it)" (Elwyn et al. 2000, 135). This implies that it may well be the case that both directive and non-directive counselling may either qualify as paternalistic or not. Independently from the content of professional advice (i.e. what concerns the criterion of directiveness), counselling processes may be deemed paternalistic if and only if they are (i) intended to promote the good of the recipient in terms of individual welfare, good, happiness, needs, interests or values, and (ii) the consent or dissent of the recipient is not a relevant consideration for the initiator of the act (see *infra* Chapter 2).

(Chamberlin 2013), (ii) to have a range of options from which to make choices (Chamberlin 2013), (iii) to participate to group and community action through the identification of common values, needs and goals (Feste and Anderson 1995, Laverack 2005), and/or (iv) to have the adequate material and economic resources to make a change in one's own life with regard to health (Chamberlin 2013). This means that relevant empowered agency is framed, from the perspective I defend from ethical grounds, as inextricably related to transformations at the interpersonal, community and institutional levels (World Health Organization 1986, Wallerstein and Bernstein 1988, Laverack 2005, Tengland 2008, 2012). And consequently, this view demands also an appreciation of the effects of empowerment in the social context in which the individual is embedded, as emphasized by scholars in Pathway 3.

In a nutshell, the normative theorization of empowerment presented through this thesis claims that the *state* of being empowered (i.e. being responsible for the pursuit of one's own health-related goals) depends also on the mastery (enhanced through non-paternalistic professional support) of the politically and socially contextual *process* of generating the goal of empowerment. As a result, a methodological evaluation of its effectiveness calls for measurements that are able to capture its enabling, health-related and community-based outcomes alike. Unfortunately, the range of literature presented in this chapter shows that such a comprehensive methodological approach to empowerment is still in need. The key message here is therefore that, what I defended as genuine empowerment (from normative grounds) in the context of EBRs, demands the development of multi-level measurements, and consequently the abandonment of the compartmental/three-tier view pulling apart its indicators of effectiveness.

Conclusions

It is clear from the analysis of the three *Pathways* of research on measurements of empowerment that growing evidence within the literature promises to produce valid and reliable tools for the evaluation of its effectiveness. However, further research is needed to bring all of these instruments to conceptual and methodological maturity. In order to ground this conclusion, I have described each of these three pathways for the establishment of measurements of empowerment. First, I showed how some scholars have focused on the *enabling* aspects of empowerment as the standard set of indicators for its effectiveness. In particular, I showed how, despite the availability of some instruments measuring psychological effects of empowerment (see Faulkner 2001a, 2001b, Kettunen et al. 2001, Kettunen et al. 2006 in Hudon et al. 2010), their methodological design entails limitations in terms of generalizability of data produced. Similar methodological issues were found also in the case of instruments for *health-related* outcomes of empowerment, namely those methodologies for the implementation and measurement of empowerment that look at the health-related outcomes of the intervention. Finally, approaches to the evaluation of outcomes of empowerment at the *community* level were discussed. Within this context, I showed that empowerment is understood as an "action-oriented concept" (Wallerstein 2006, 18) with a commitment to the removal of context-specific social barriers to health through a wide range of strategies – from education and critical consciousness raising, to advocacy and participatory policy-making for the reduction of health inequalities (Tones 1998, Wallerstein 2006). Such wide range of domains covered by community approaches to empowerment, I concluded, is the major cause for the lack of cross-contextual indicators for its measurement.

Then I turned to the potential methodological approach required to assess the effectiveness of the normative understanding of empowerment I defended in Part 1. With regard to this, I argued that the *bundle* of substantive domains (i.e. anti-paternalism, health, responsibility) at the basis of the approach within EBRs calls for the development of multi-level empowerment measures, which are able to capture its enabling, health-related and community-based outcomes alike. The recognition that such a methodology for measuring empowerment may be required in the context of EBRs fleshes out the need to abandon the mutually exclusive *Pathways* of research on the effectiveness of empowerment, in order to embrace the development of methodologies capturing all of this (normatively) relevant dimensions of the concept.

Even though I side with scholars pointing to the fact that there is no universally valid participatory medicine which empowers patients (Kelty et al. 2014, Kelty and Panofsky 2014), I hope that my analysis of the substantive foundations of empowerment can be regarded as a useful attempt to bring the approach and its applications to “conceptual maturity” (Herbert et al. 2009, 126) in the context policy-making. The substantive dimensions of the concept I identify in the thesis (relating to anti-paternalism, health, and responsibility), demand to be further tailored to a specific context and empirically assessed. The aim of the present chapter was thus to provide a foundation to the search of scalable and generalizable measurements of empowerment. Characterising the ethical underpinnings of empowerment could indeed render the characteristics of desirable power relationships in medicine well-defined (Prainsack 2014, *forthcoming*), and hence provide specific boundaries as to the conditions, variables and outcomes that is worth measuring in a particular application of the empowerment language. This, as the analysis above wishes to show, may not necessarily come at some cost for the distinctive ethics of active, context-sensitive involvement and participation associated with the empowerment approach (Freire 1972, Tengland 2008, Tengland 2012).

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Part 2

Chapter 6. The promises of epigenomics for Personalised Medicine

Introduction

This chapter elucidates how novel approaches to prevention, diagnosis and treatment brought about by epigenomics are a fundamental tenet of the personalization project inaugurated by what I called EBRs. In particular, I start from a map of the contribution of epigenomics to the development of Personalised Medicine (PM) across three of the most relevant domains of healthcare. These three areas of medicine are cardiovascular diseases, neuropsychiatric disorders and cancer, which together account for 74% of the total causes of death in high-income countries (World Health Organization 2010). This analysis points to the vast range of health benefits that epigenomics science will most likely produce for the wider society, but also to its unique potential to move ahead the implementation of PM. Briefly put, what I will show is that epigenomics may bring into the picture of PM the elements of time, variability and dynamic adaptations to environment (in its broadest sense, from the intrauterine environment to the physical, nutritional and social environment) as fundamental facets of individual health and illness.

Consequently, a consistent number of promising approaches within developing epigenomic PM are reviewed throughout the chapter. What I will highlight from this analysis is, however, not only how the promise of epigenomics to make increasingly visible the 'contextual nature' of health (i.e. illuminating the biological mechanisms underlying the interaction between lifestyle, living conditions and individual health) has a significant impact on medicine, but also how careful scrutiny should be granted to the social program (Landecker and Panofsky 2013) potentially instated by epigenomic medicine. The individualization of care entailed in epigenomics, should in fact be poised with some potential concerns arising from its participation to the "sociotechnical imaginary" (Jasanoff and Kim 2009, Jasanoff and Kim 2013) of PM described in Chapter 1. Building upon evidences of the malleable mechanistic underpinnings of the environmental and developmental roots of health, I will emphasize how epigenomics may constitute a powerful biotechnological resource to successfully rise to the empowerment project of EBRs (and PM) identified in Chapter 1. On the one hand, epigenomics is finally able to grant PM an appreciation of the biological variability in disease development and treatment responses across the general population. By confronting the complex interplay of individual predispositions, environmental triggers and life experiences at the basis of disease aetiology, epigenomics is *the* unifying molecular language that both makes visible (Nowtony and Testa 2011) and manageable (Meloni and Testa 2014) the unique biological and biographical makeup determining individual health. Very much like other biotechnologies of contemporary biomedicine (e.g. genomics, proteomics pharmacogenomics), epigenomics fuels the reconfiguration of the fundamental categories of medicine under the language of molecular biology. In this respect, epigenomics provides solid epistemological and technological ground to the project of PM and its emphasis upon empowerment, because it represents a set of scientific advancements, in the understanding of disease and illness, dissecting the interaction among the players behind individual's health. On the other, the reversibility and malleability of epigenetic modifications entails the danger of further instating the emphasis upon individual responsibility in PM, thus fuelling also the political narrative of empowered and proactive agency in healthcare at its basis. By showing how social and environmental influences inherently affect individual health, epigenomics may in fact be taken to support normative claims of responsibility to protect and change one's epigenome from the wide range of external insults under individual control (Meloni and Testa 2014).

It is not only worth noting, therefore, that epigenetic science will profoundly affect the achievement of a new model of medicine established by the proponents of PM, but also that the emerging model of PM can finally reinforce, through epigenomic science, its constitutional project of the *empowered patient citizenship* discussed in Part 1. Whether or not the potential concerns arising from this recognition can be met from the empowerment perspective defended throughout this work will then be the subject of the next and final chapter of the thesis (see *infra* Chapter 7).

Epigenetics and its 'omics descendant

Identifying a received view on the meaning of 'epigenetics' is no easy task. Since its original coinage by Conrad Waddington in 1942 – as "the branch of biology which studies the causal interactions between genes and their products, which [in turn] bring the phenotype into being" (Waddington 1942, 18) – the term has come to assume very different meanings to different scientific communities. First, the term has been widely used by functional morphologists with reference to the numerous processes and cellular interactions that lead to morphogenesis and organogenesis. From this long-standing perspective (Van Speybroeck 2002), the word "epigenetic" is an adjective of 'epigenesis', meaning that it refers to all phenomena that are inherently associated to processes of organism development or genesis (Herring 1993). This means that when Waddington invented the term 'epigenetics', the role of genetics in developmental processes was not considered to be central (Jablonka and Lamb 2002). Rather, if we wanted to capture the essential feature of this original formulation of the concept, it would be worth emphasizing how biological questions related to organism *development*, beyond genetics, play a fundamental role in its original understanding:

> Some centuries ago, biologists held what are called "preformationist" theories of development. They believed that all the characters of the adult were present in the newly fertilized egg, but packed into such a small space that they could not be distinguished with the instruments then available. If we merely consider each gene as a determinant for some definite character in the adult (as when we speak loosely of the 'gene for blue eyes, or for fair hair'), then the modern theory may appear to be merely a new-fangled version of the old idea. But in the meantime, the embryologists, who are concerned with the direct study of development, have reached a quite different picture of it […]. This is the theory known as epigenesis, which claims that the characters of the adult do not exist already in the newly fertilized germ, but on the contrary arise gradually through a series of causal interactions between the comparatively simple

> elements of which the egg is initially composed. There can be no doubt nowadays that this epigenetic point of view is correct (Waddington 1952, 155).

It is with the advent of genetics and molecular biology, however, that the term ‘epigenetics’ has acquired further distinct characterizations. This view originates from an alternative etymological interpretation of the term (Nanney 1959), which stresses how the prefix *epi* (‘above’) in ‘epigenetics’ refers to ‘genetics’ rather than ‘genesis’, thus coming to assign it the meaning of an upper and sequence-independent layer of gene regulation. Otherwise stated, this second interpretation defines the term as the study of those molecular processes that cannot be explained by genetic principles (Goldberg et al. 2007), or as “the study of mitotically and meiotically heritable *changes* in gene function that cannot be explained by changes in genetic sequence” (Bird 2002, 6; emphasis added). It is worth noting here how crucial it is, for the sake of drawing the semantic boundaries of the term, that only some kinds of ‘changes’ in gene function count as epigenetic ones: a theoretical endeavour that may raise some significant issues for contemporary biology (Jablonka and Lamb 2002). The main difficulty of this definition is in fact that, although it usefully distinguishes between DNA-based and non-DNA-based inheritance of phenotypes, it provides no simple criterion to identify what are the relevant epigenetic changes (Jablonka and Lamb 2002). On the one hand, a broad view would claim that ‘changes’ in each and every level of function beyond the level of genes counts as epigenetic in this definition. In this respect, “the transcriptome, the proteome and the various omic- slices into which life’s complexity has come to be parsed along the biochemical classification of its constituent molecules” (Meloni and Testa 2014, 4) fall within the scope of term. On the other, a different and narrower view would restrict this scope by discriminating among sources of the information that gets stably integrated with DNA. To this view, only those “change[s] in gene function that [persist] even when the initial trigger is long gone [and] that [do] not involve a change in gene sequence or structure” count as epigenetic (McGowan and Szyf 2010, 67). In light of this second and more recent meaning of the term, an epigenetic trait is “the molecular memory of past stimuli”, or the set of chemical marks and signals that allow a cell to "remember past events, such as changes in the external environment or developmental cues" (Bonasio et al. 2010, 612). In doing so, the recent meaning of epigenetics turns the field into the study of the molecular roots of organism development, thus re-comprising and re-elaborating the semantic space originally covered by the concept. Contemporary epigenetics brings to forth the contextual and molecular nature of developmental processes by highlighting how epigenetic patterns are both a stable and plastic process, as well as an *acquired and/or heritable* phenotype (Feinberg 2008), consisting of multiple changes in a chromosome that do not alter the DNA sequence:

> Because of this, there is a continuity between epigenetics in Waddington's sense and epigenetics today: both focus on alternative developmental pathways, on the developmental networks underlying stability and flexibility, and on the influence of environmental conditions on what happens in cells and organisms (Jablonka and Lamb 2002, 88-89).

To recapitulate, looking for a definition of epigenetics means firstly resorting to the common use of the word in experimental practice. Within this context, epigenetics arose essentially as "the study of the mechanisms of temporal and spatial control of gene activity during the development of complex organisms" (Holliday 1990, 329), and has recently become shorthand for the set of chemical marks that affect gene expression upon certain environmental stimuli or during cell state transitions (Riddihough and Zahn 2010). At a general level, the operational definitions of the term presented here reveal that epigenetics has been historically concerned with a progressive detachment from the gene-centric focus of molecular biology (Rivera and Ren 2013). Briefly put, epigenetics adds an additional layer of complexity to the view that the genotype determines the phenotype. By plunging into the open question of phenotypic variation in human populations and individual organisms, epigenetics has gradually come to focus on how genomic information gets directed both spatially and temporally by a number of non-genetic inputs contributing to phenotype. This is in essence, according to some authors (Landecker and Panofsky 2013), the paradigm shift that stems from the epigenetic endeavour. After a few decades of dominant genetic logic, seeking to identify the sequence variation that underlies different physical and behavioural outcomes, the epigenetic logic seeks to establish "how different bodily outcomes arise from essentially similar genetics" (Landecker and Panofsky 2013, 336). Let us now briefly turn to the analysis of some of the most studied epigenetic mechanisms, and their application to human health, before problematizing further the societal aspects of competing epigenetic epistemologies (Meloni and Testa 2014) in Chapter 7.

Nuclear structure and the 'epigenome'

In the nucleus of eukaryotic cells, DNA is packed together with proteins into a highly complex macromolecular structure termed chromatin (Bernstein et al. 2007). There are several levels of DNA compaction that can be achieved during different phases of the cell cycle, from the looser compaction required by DNA replication in S Phase up to the hypercondensed state that is represented by metaphase chromosomes. Yet, the base unit of DNA packaging in eukaryotes is represented by the nucleosome, whose structure was firstly elucidated in 1997 (Luger et al. 1997). Each nucleosome is composed by a strand of approximately 147 DNA base pairs wrapped around a globular octameric protein core, formed by 2 copies of each of the histone proteins H2A, H2B, H3, H4. The H1 linker histone and its isoforms also participate in chromatin compaction by interacting with the nucleosome near the entry and exit points of DNA (Allis et al. 2007). It is by zooming in and out on these scales of nuclear organization (DNA, histones, nucleosomes, chromatin) that we can meet the most characterized and well-studied epigenetic mechanisms.

Much of today's epigenetic science means in fact studying the multiple modifications to which DNA or histone proteins are subjected, and consequently how such modifications affect overall nucleosome and chromatine structure (Goldberg et al. 2007). In addition, the last few years have seen an overwhelming technological development, which finally made possible not only to assay such modifications at the level of a single gene or modification, but also to describe them across the whole genome (Callinan and Feinberg 2006). This is the emerging science that goes by the name of *epigenomics*, and that consists of a "global, comprehensive view of sequence-independent processes [namely, the 'epigenome'] that modulate gene expression patterns in a cell" (Rivera and Ren 2013, 39). By resorting to cutting-edge technologies of next-generation sequencing (Koboldt et al. 2013), epigenomics promises to survey the entire set of epigenetic modifications in the genome in an unbiased, nucleotide-based and comprehensive manner (Rivera and Ren 2013). This unprecedented and monumental shift in assay capacity, can therefore elucidate the unique gene expression patterns of each cell type, thus answering to the question of how cells that are invariant with respect to their DNA sequence can actually give rise to very different tissues in our bodies (Callinan and Feinberg 2006).

The most characterized covalent modifications that can affect chromatin function include DNA methylation and post-translational histone modifications (Callinan and Feinberg 2006). In mammals, DNA methylation on the fifth position of cytosine (5mc) is mainly restricted to the CpG dinucleotides, and commonly occurs at centromeres, telomeres, and repeated sequences. CpG-rich DNA stretches, or "CpG islands", are usually about 1000-bp long and frequently unmethylated. CpG islands are usually associated with regulatory functions, located at the 5' of genes, and can be identified in about 70% of all mammalian promoters. This evidence suggests a role for DNA methylation in the global maintenance of the genome, and several functional models have been proposed (Weber and Schübeler 2007). First, a number of genetic studies indicate that global hypomethylation is associated with increased genome instability in mammalian cells (Dodge et al. 2005). In particular, this connection has been well documented in the context of cancer, where many cells display global hypomethylation associated with increased chromosomal instability and tumour progression (Weber and Schübeler 2007). Second, DNA methylation has been hypothesized to play an important role in cell-type-specific gene expression, on the basis of its potential to silence promoters. To this view, the main role played by methylation of CpG islands lies in transcriptional regulation and transcriptional silencing (Deaton and Bird 2011), which is performed by three different DNA methyltransferases (DNMTs) proteins in higher eukaryotes (Okano et al. 1999). DNA methylation has been regarded as a stable DNA modification until 5-hydroxymethylcytosine (5hmC) was discovered, suggesting for the first time that 5mC mediate lineage restriction by silencing the expression of portions of the genome that are not specific to a given tissue (Kriaucionis and Heintz 2009). Quite the contrary, global DNA methylation technologies have recently progressed beyond the narrow view that 5mc is only a stable repressive mark (Rivera and Ren 2013). DNA methylation is currently regarded to display a variable pattern among individuals, and an epigenetic mark that is dynamically deposited and removed on the basis of environmental influences. This recognition opens up a whole range of possibilities for the study of phenotypic diversity and disease susceptibility, pointing to the critical role of DNA methylation as a proxy for embedding environmental cues in the genome through imprinting, gene (in)activation and chromosome inactivation (Suzuki and Bird 2008).

As mentioned above, the second and most widely studied family of epigenetic mechanisms are the modifications of histone tails and their globular domains. Histones are in fact the substrate of more than 130 covalent modifications (Rivera and Ren 2013), which can alter the structural organization of the nucleosome and ultimately influence DNA access, conformation and function. More specifically, post-translational modifications of histones can function as docking sites for proteins and complexes, thus establishing global chromatin domains that are functional to the execution of different DNA-based programs in different cell types, such as genomic imprinting, transcription, DNA repair, DNA replication and chromosome condensation (Kouzarides 2007). Histone modifications have been shown to serve both purposes of activation and silencing of genomic regions, and can in general be considered as binding substrates for the recruitment or exclusion of protein complexes (Rivera and Ren 2013). The N-terminal tails of histones emerge from the octameric core and constitute the most dynamic regulatory domain of histones. Several post-translational modifications, mainly targeting lysines and arginines, have been described. Such modifications include acetylation, methylation, phosphorylation, ribosylation, ubiquitylation and sumoylation (Karlic et al. 2010). One of the main consequences of these modifications is the alteration of the surface charge of histones and the ensuing change of the overall strength of histone-histone and histone-DNA interactions, with a profound effect on the compaction state of chromatin. As an example, phosphorylation (Wei et al. 1999) or acetylation (Görisch et al. 2005) can loosen the chromatin fiber by reducing the overall positive charge of the histone tail, thus making DNA more accessible to transcription factors and therefore potentially more transcriptionally active. Histone modifications can also favour or hinder the recruitment of other proteins to the modified histone tails. The concerted action of histone modifications and non-histone proteins contributes to the recruitment of protein complexes that can allow mRNA transcription, DNA repair or replication, and chromosome condensation (Kouzarides 2007). Importantly, most of these modifications are dynamic, and enzymes have been isolated that can add and remove histone marks. Thus, for example, histone acetylases (HATs) and de-acetylases (HDACs) have been described, as well as histone methyltransferases (HMTs) and demethylases (KDMs) (Karlic et al. 2010).

Histone lysine methylation is central to processes of cellular differentiation, since the expression of genes involved in differentiation is dynamically regulated through changes in histone methylation at specific lysines. Most notably modifications of H3K27 (i.e. histone 3, lysine 27) is associated with transcriptional repression, while H3K4 is associated with transcriptional activation. Genome-wide analysis showed that H3K27me3 (i.e. tri-methylation of histone 3, lysine 27) labels transcriptionally repressed domains that are present in Embryonic Stem (ES) cells, which extend to differentiated cell types in order to maintain cell type-specific repression (Kouzarides 2007). Functionally, these regions might serve for lineage restriction during differentiation as they cover only approximately 4% of the genome in undifferentiated mouse ES cells, compared to 31% in differentiated ES cells (Wen et al. 2009).

By zooming out on the hierarchy of genomic organization, we then find the epigenetic patterns of regulation that go beyond modifications of DNA sequences and histone proteins. The positioning of nucleosomes along the genome is in fact another important, yet highly debated, epigenetic player (Rivera and Ren 2013). As mentioned above, our genome at its most basic level is constituted by "repeating units of 147 base pairs wrapped 1.7 times around each nucleosome with varying distances of linker DNA between each unit" (Rivera and Ren 2013, 44). Yet, this simplistic model overlooks the role that nucleosome positioning can play in both inhibiting and promoting factor binding, as well as in regulating the expression of the genome (Bell et al. 2011). On the one hand, the position of nucleosomes along the strands of DNA obstructs or reveals specific DNA sequences. Roughly put, depending on the *loci* of the genome that are wrapped around histones, some portions of DNA may be more or less accessible to transcription factors. On the other, the plethora of modifications on histone tails and globular domains showed above is in itself dependent from nucleosome positioning, which affects their capacity for recruitment of transcriptional regulators. As showed by Rivera and Ren (2013), the contribution of nucleosome positioning to disease aetiology is still in its infancy. Most of the knowledge regarding the consequences of aberrant nucleosome positioning still regards studies of animal models, such as yeast and fly (Jiang and Pugh 2009). However, this information remains of pivotal importance for the understanding of diseases associated to unfavourable composition and packing of the DNA sequence (Rivera and Ren 2013).

Finally, another level of epigenetic patterning deserves here a special mention. The last few years have in fact experienced the "collision" (Bernstein and Allis 2005) between two separate worlds of molecular biology: noncoding RNAs on the one hand, and chromatin on the other. As showed by Goldberg and colleagues (2007) the reason for including RNA activity among epigenetic mechanisms lies in its newly discovered role in the regulation of chromatin states. Accumulating evidences in a variety of model systems show in fact that noncoding RNAs are responsible for the formation of "active" (euchromatic) or "silent" (heterochromatic) chromatin domains, one of the pivotal domains of epigenetics. A paradigmatic example of noncoding RNAs' involvement in chromatin (in)activation comes from the study of mechanisms of dosage compensation in animal models. Within this context, it has been shown that noncoding RNAs allow to "choose the dosage" of expression between the chromosome coming from paternal lineage and the one inherited from the mother: an epigenetic mark that persists even after cell division (Heard 2004, in Bernstein and Allis 2005).

In particular, RNA-mediated epigenetic silencing of genes happens either by post-transcriptional (PTGS) and transcriptional (TGS) RNA interference.

It is on the basis of these two different levels of RNA-chromatin interaction that the view holding noncoding RNAs as an additional epigenetic player is still in need of complete appreciation. On the one hand, researchers have shown that RNAs act in concert with various components of the cell's chromatin and the DNA methylation machinery to achieve stable *transcriptional* silencing. TGS-evoking RNAs are thus “more clearly epigenetic” (Goldberg et al. 2007, 637) since they squarely fall within currently dominant definitions of what counts as epigenetic and what does not. Namely, RNA-mediated TGS pertains to non-DNA-based *changes* in gene function, which can induce effects that can be inherited through cell division (Allis et al. 2007). On the other, other scholars have argued for not considering PTGS-inducing RNAs to be epigenetic in nature, since they do not regulate the expression of the genome, but rather affect processes of protein translation (Bernstein and Allis 2005). It is because of this “detachment” from the DNA sequence, that the epistemic status of RNAs as a component of cellular epigenetic machinery is currently under dispute. Nevertheless, it is worth noting how, although the molecular basis of crosstalk between RNA and chromatin remains unclear, understanding how these states are established and maintained during the development of an organism can be considered one of the pressing epigenetic imperatives in contemporary biology.

The power of epigenome mapping techniques

Epigenetics and its ‘omics descendant are, in other words, a moving target in contemporary biomedicine, which is liable to more than one interpretation. A profound disagreement can be currently identified in the definition of the terms ‘epigenetics’, as well as on the boundaries of what constitutes an epigenetic phenomenon (Meloni and Testa 2014). Nevertheless, it is undoubted that the field has experienced a remarkable expansion in the last few years. Propelled by the technological development of epigenome mapping techniques (Rivera and Ren 2013), epigenomics is in fact widely considered the “next big thing” in biomedicine

(Ebrahim 2012). Yet, the technological power of next-generation sequencing techniques is only but one of the factors contributing to the rise of epigenomics. Another important one is in fact the formation of several research consortia that, worldwide, are currently trying to standardize the field and to specify the blurred boundaries of relevant epigenetic science. Modelling after the success of the Human Genome Project (Lander 2011), these consortia include the US Roadmap Epigenome Project, the ENCODE Project, and the International Human Epigenome Consortium (IHEC), which find their European counterpart in a number of national and supranational initiatives such as the Italian EPIGEN consortium, DEEP, Epigenesis and Blueprint.

It is thus also because of the standardized experimental protocols, data analysis procedures, and most importantly the large amounts of data sets publicly released by these consortia that epigenomics has grown dramatically in the last few years. As reported by Rivera and Ren (2013, 47), "the number of epigenome maps generated has grown exponentially, from a handful in early 2007 to several thousand as of today", meaning that the epistemic contribution of epigenomics to the understanding of human biology and health is growing at a very rapid pace. For instance, the ENCODE Consortium has recently released comprehensive maps of chromatin modification states in 46 human cell types, highlighting how distinct patterns of histone modification, spanning across approximately 56% of our genome, are indicative of the specific biochemical activities of each cell type (ENCODE Project Consortium 2012). Otherwise stated, epigenome mapping techniques promise to illuminate the set of chromatin modifications, at the basis of tissue specification, by segmenting the regions of the genome specific to each cell type.

Rather than simply being a collection of elements, epigenomics is bestowed the capacity to finally provide a comprehensive view of the nuclear "regulome" (Rivera and Ren 2013, 48) in its three-dimensional space. As argued by Haig (2012), it is reasonable to expect that the epigenomic research will soon annotate completely the catalogue of functional variants of the human genome, and consequently will bring a valuable contribution to the understanding of human health and disease development. As detailed below, epigenomic maps are already in the process of rendering their contribution an essential element of the understanding of pathogenesis in the most common diseases. The question we face today is therefore not *whether* epigenomics may constitute an essential facet of the 'personalization project' in medicine (Chadwick 2013) described in Chapter 1. Quite the contrary, what we should ask ourselves is 'what are the domains of medicine where these new technologies and tools will firstly becoming available?'

The contribution of epigenomics to Personalised Medicine (PM)

This section explores the potential of epigenetic science as a key driver for the development of PM. As we will see, the application of epigenetics (and increasingly of epigenomics) to different domains of healthcare is likely to further instate the focus on the individual patient at the basis of the sociotechnical imaginary (Jasanoff and Kim 2009, Jasanoff and Kim 2013) depicted by PM (see *infra* Chapter 1). Medical applications of epigenetics encompass in fact a wide range of developments that will constitute an important driver of PM. First, the reversible nature of epigenetic changes "gives drug developers and biomedical researchers reasons to dream about how their efforts might reverse changes that contribute to disease" (Marx 2012, 146). The plasticity and malleability of the epigenome, as well as its unique individual patterning, is widely considered as a promising target for the development of pharmaceutical compounds (Marx 2012). The rise of epi-drugs for different tumour types, eight of which have already been approved by the Food and Drug Administration (FDA) and/or the European Medicines Agency (EMA) (Damjanovicova, *unpublished data*), already testifies the impact of epigenomics on clinical treatment of common diseases.

Second, the technological development of epigenomics is also a promising field for a steep increase in the number of tissue and individual-specific biomarkers for predictive diagnostics and screening tests. As we will see below, molecular biomarkers of changes in epigenetic modifications of a number of genes are already being used to guide clinical decisions in cancer, and more of them are on their way. In addition, the last few years have also witnessed the appearance of companies (e.g. Oncomethylome Sciences, Epigenomics

AG, Sequenom, Exact Sciences) beginning to offer a range of *in vitro* tests for several epigenetic markers in cancer treatment. For instance, the company Exact Sciences has recently received approval from the FDA (decision held on August 11, 2014[25]) to market a combined four methylation markers test for early detection of colon cancer. As reported by the FDA, this test fared much better than commonly used methods for non-invasive screening tests as to its sensitivity, both with regard to detection of colon cancers and advanced adenomas.

Third, epigenetics might well contribute also to the preventive aspects of PM. As research on epigenome maps progresses, epigenetic markers may account for environmental and lifestyle exposures responsible for disease development, well in advance the emergence of clinical symptoms (Relton and Davey Smith 2010). Several factors are currently under study as to their influence on aberrant epigenetic patterning. Nutritional factors such as high-fat diet (Widiker et al. 2010), environmental pollutants (Baccarelli et al. 2009), smoking (Philips and Goodman 2009) have all been shown to contribute to plastic modifications of the epigenome across the individual life span with potentially disruptive health consequences. The potential of epigenome mapping techniques to provide us insights on the aberrant effects of environmental and lifestyle exposures, hints therefore at the possibility that unique individual epigenetic read-outs may become commonplace in the future of medicine. A simple blood test, may in fact constitute the viable means to monitor individual epigenetic patterning in its plastic responsiveness to environmental cues, and consequently constitute precious knowledge for the prevention of diseases in the general population. If the costs of sequencing will continue to plummet (Koboldt et al. 2013), genome sequencing and epigenome mapping may come into being an integral part of healthcare routine for many patients, and perhaps even part of regular medical examination.

Epigenomics and cardiovascular diseases

Cardiovascular diseases (CVDs) are widely acknowledged as the biggest cause of deaths across the world (World Health Organization 2011). Although declining in most European countries,

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[25] More information available at the following web address: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm409021.htm (Last Accessed: 29/9/2014).

the prevalence of CVDs is currently increasing astonishingly in low and middle-income countries, and will most likely remain a global major health concern for the next two decades. No doubt, 'omics' technologies (e.g. genomics, epigenomics transcriptomics, proteomics, and metabolomics) promise to fundamentally change also our understanding of CVDs and consequently to improve strategies to tackle them. In particular, epigenomics has emerged as one of the most promising approaches that will help to address gaps in our knowledge on CVDs aetiology (Ordovàs and Smith 2010). As we have seen above, epigenetic science can provide an understanding of all those mechanisms allowing organisms to quickly react to environmental changes. In this respect, epigenetics is therefore a promising candidate to illuminate the link between genes and the wide range of environmental and lifestyle-related cues (e.g. tobacco use, physical inactivity, diet, overweight, pollutants) associated to incidence and morbidity of CVDs. Individual variation in the epigenetic modification of genes can explain a larger part of the phenotypic variation observed in humans better than differences in genotype alone (Baccarelli et al. 2010).

A first set of evidences pointing to the role of epigenetic modifications in CVDs-related phenotypes, concerns data on genomic DNA isolated from human atherosclerotic lesions, which is generally held to be globally hypomethylated (Ordovàs and Smith 2010). Secondly, another set of studies has reported specific methylation patterns of changes (usually hypermethylation) in the promoter region of genes associated with atherosclerosis (Dong et al. 2002). Third, inflammatory states – which play a major role in the formation, progression, and rupture of atherosclerotic states – have been frequently observed to involve epigenetic changes (Shanmugam and Sethi 2013). Different studies on peripheral blood lymphocytes in patients with coronary heart disease have however reported both increases and decreases in methylation status (Turunen et al. 2009). This means that knowledge on the involvement of methylation patterns in CVDs should be taken with caution, since the field is still in its infancy, and the evidences still disputed and inconsistently reported. Whether epigenetic changes have a causal role in pathogenetic features of CVDs, or whether they merely represent a consequence of the ongoing pathological process, remains thus unclear. However, it is worth noting that epigenetic science promises to explain the poorly understood environmental and dietary effects on human metabolism, and the differences in the incidence of CVDs across the population. The emphasis of current research is in fact on the environmental roots that cause epigenetic changes, whose plasticity triggers aberrant processes related to CVDs risk (Ordovàs and Smith 2010).

Within this context, a seminal study by McGuinness and colleagues (2012) has recently come to the attention of both media and social analysts because of its proposal of methylation states as a "bio-dosimeter" of socioeconomic status (SES) (Landecker and Panofsky 2013, Meloni and Testa 2014). The study provides evidences that levels of global methylation across the genome (i.e. total DNA methylation levels as a percentage of total DNA in the samples) mirror SES. To show this, researchers used as a base model an already established cohort of subjects from a previous study, named "pSoBid", which clustered citizens of Glasgow (Scotland) on the basis of "deprivation groups". Blood samples from these participants were then analysed as to their levels of global methylation, revealing that SES, lifestyle factors (smoking, diet, housing, physical activity) and a set of biomarkers for CVDs (e.g. blood pressure, cholesterol, glucose levels) correlate with epigenetic status, and that global DNA hypomethylation associates with the most deprived group of study participants (McGuinness et al. 2012, 7).

A related, and yet different, example of how molecular environmental epigenetics can provide us insightful knowledge on social conditions and their impact on health, comes instead from a study on the long-term consequences of the Dutch Hunger famine, which took place during the winter of 1944-1945 (Heijmans et al. 2008). The events concerning this famine escalated when the Dutch government called for a national railway strike to hamper the manoeuvres of the German army. As a consequence, German authorities imposed an embargo over the western part of The Netherlands concerning all food supplies over the month of October 1944. During this period, official rations remained well documented (mostly bread and potatoes were available in little quantity), thus allowing researchers to establish that, as of April 1945, concerned Dutch citizens were surviving on as little as 500 calories per day. The unique features of this famine (mainly its intact reports on the side of healthcare and local authorities) enabled Heijmans and colleagues to assess its long-term epigenetic and health consequences over the population. In particular, investigators found out that individuals who were exposed *in utero* to the deprivation of the famine showed significant reductions in the methylation patterns of the IGF2 gene in comparison to their unexposed siblings: a key factor in human growth and development that is maternally imprinted, and is physiologically tied to diabetes (Heijmans et al. 2008). In addition, a sex-specific increased risk of obesity and CVDs-related deaths has been reported by this study among those whose mothers were exposed to famine early in gestation, up to six decades later. Since extensive modifications of the epigenome occur in two phases during development (during fertilization and during maturation of primordial germ cells), it is likely that these two time points represent very sensitive time periods during which exposure to extreme conditions might have lifelong consequences. Indeed, more and more research focuses on epigenetics in embryonic, fetal and neonatal development to understand the basis of adult onset disease (Damdimopoulou et al. 2012).

Taken together these observations confirm the view, anticipated above, that a new conceptual model for the understanding of disease aetiology of CVDs emerges from evidences in the studies of their epigenetic bases (Baccarelli et al. 2010). Studying the plastic and dynamic changes in the epigenome over the life course may constitute insightful knowledge on the adaptive and deviant gene-expression states at the basis of CVDs. The fact that age, sex, and cardiovascular risk factors can be mapped onto specific patterns of DNA methylation, constitutes an attractive set of knowledge that, in principle, might help to explain how environmental and lifestyle factors can impose aberrant and individually unique gene expression patterns in an individual's lifetime. Consequently, it is reasonable to argue that epigenomics currently promises to provide valuable ground for the prevention and treatment of individual cardiovascular risk (Baccarelli et al. 2010). It is not difficult to imagine in fact how a personalised epigenomic read-out, following the individual throughout the life span, may constitute an important player for the development of individually tailored management of CVDs even in their asymptomatic stage.

Epigenomics and neuropsychiatric disorders

Another set of evidences, pointing to the role of epigenomics for the personalization of healthcare services, relates to the epigenetically regulated gene expression patterns in the arena of psychiatric illness (Persico and Burgeron 2006). First, a number of studies have reported an association between prenatal and early life epigenetic mechanisms and long-term psychiatric outcomes. Data from both human populations and animal models have found that responses to psychosocial stress, epigenetically mediates the functioning of glucocorticoid receptors (Meaney and Szyf 2005). In particular, these evidences suggest that epigenetic changes fostered by individual upbringing, or behavioural stimuli have long-lasting neurobiological consequences caused by brain region–specific changes in signalling and neuroplasticity (Pascual et al. 2009). Research findings on drug abuse show also that addictive behaviours may follow a similar pattern. Emerging data suggest that epigenetic regulation may be "the molecular basis of drug-induced changes in gene expression in brain reward regions" (Wang et al. 2013, S17), thus also shaping the neural and behavioural plasticity underlying addiction-related habits. Taken together, all of these studies point to a promising aspect of epigenomics, which could finally elucidate the link between inherited predispositions, environment, behavioural stimuli, and exposure to drugs, hence providing a molecular basis for the long-lasting alterations in gene expression that influence susceptibility to impaired stress response mechanisms as well as addictive behaviours (Wong et al. 2011).

Second, epigenetic factors have also been suggested to play a preeminent role in the aetiology of neurodevelopmental diseases, such as autism spectrum disorders (ASDs). Differently from what was commonly held (Schanen 2006), ASDs (including autism, Asperger disorder, childhood disintegrative disorder, etc.) may not be solely genetic in origin with a polygenic, epistatic model largely dominating biological understandings of this family of conditions. Quite the contrary, the last few years have seen a proliferation of lines of evidences pointing to the role of environmental and epigenetic factors in ASDs (Persico and Bourgeron 2006). The reason behind this paradigm-shift in the understanding of the complex phenotypes behind ASDs lies in the inconclusive nature of studies focusing on the interacting genetic *loci* contributing to ASDs susceptibility, which "has been estimated to range between two and 15 genes of varying effect" (Schanen 2006, 138). These risk alleles for ASDs have been in fact "remarkably elusive" (Schanen 2006, 138), despite the considerable effort to identify the genetic basis of autism-related diseases. One explanation for the limits of an exclusively genetic aetiology of ASDs lies in the fact that this unifying label hides a significant clinical heterogeneity of conditions, ranging from dramatic debilitating mental impairments to mild personality traits. In this respect, the purpose of finding a common genetic ground for a variety of complex mental and behavioural phenotypes may be considered as the main limitation hindering the advancement of these studies (Persico and Bourgeron 2006). Yet, the underlying genetic heterogeneity within and among the diagnostic categories in ASDs, may only partially explain the lack of progress on the understanding of their developmental origins. To this second view, the obstacles encountered in mapping the risk alleles of ASDs are rather due to an incomplete model of inheritance and development of these diseases, which does not take into account the role of environmental and epigenetic factors contributing to them (Ladd-Acosta et al. 2014). Reinforcing this idea, is also the striking rise in the incidence of ASDs observed in the last couple of decades (from 2-5 to 15-60 children per 10000 affected by these disorders), as well as the dramatic behavioural and neuroanatomical differences displayed by monozygotic twins discordant for an ASDs diagnosis (Persico and Bourgeron 2006). The fact that genetically identical twins display significantly different disease-related phenotypes points to the need of including contributions of acquired epimutations and/or epigenetic mechanisms in the underlying genetic susceptibility to ASDs (Schanen 2006). In particular, epigenetic modifications including cytosine methylation (Ladd-Acosta et al. 2014), genomic imprinting and post-translational modification of histones (Grafodatskaya et al. 2010) qualify as potentially insightful mechanisms for modulation of gene expression that can be influenced by exposure to environmental factors and parent of origin effects.

Finally, epigenetic mechanisms such as DNA methylation and histone modifications have also started to be described for neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease, and Huntington's disease, as well as in other neurological disorders such as multiple sclerosis, epilepsy, and amyotrophic lateral sclerosis (Urdinguio et al. 2009). In particular, relevant gains (hypermethylation) or losses (hypomethylation) of methylation are currently under study with regard to their potential role as biomarkers for each of the disorders listed above, or as promising targets for DNA-demethylating drugs. For instance, altered DNA-methylation patterns have been reported in Alzheimer's disease, with regard to the promoter *loci* of two important genes (S100A2 and SORBS3) regulating synaptic pathways (Urdinguio et al. 2009), together with a number of histone modifications (Balazs et al. 2011). Stressing the importance of epigenetic modifications characterising neurodegenerative diseases is of utmost importance for the understanding of their disease aetiology, since genetic mutations can account only for 5% of Alzheimer's disease cases (Mastroeni et al. 2010). These diseases are in fact largely explained by lifestyle and environmental risk factors, which have the greatest impact in terms of prevention and delayed onset of Alzheimer's disease, as showed by epidemiological studies (Balazs et al. 2011). Combined together, these evidences indicate that epigenetically mediated cardiovascular risk factors, diabetes and metabolic disorders could also provide an explanation for the onset of Alzheimer's and other neurodegenerative diseases. Careful experimental studies are thus required to assess the role of CVDs epigenetics in neurodegenerative disorders, and especially its potential to illuminate individual risk and susceptibility to disease development.

Potentially, epigenetics may reveal what kind of lifestyle triggers are required for neurodegeneration, how many and what insults account for pathogenesis, as well as how brain cells react mechanistically to environmental and lifestyle-related stimuli in a way that alters epigenetic marks (Mastroeni et al. 2010): all of this, with a resolution that gets to the level of individual experiences, upbringing and lifestyles. This promising pathway for the understanding and treatment of neurodegenerative disorders calls therefore for the establishment of reproducible profiles of the DNA methylomes and histone modifications of these diseases that could generate single markers to test in healthy and disease-associated populations (Balazs et al. 2011).

Excitement for a significant role played by epigenetic modifications in neurological diseases is, in other words, increasingly building in contemporary biomedicine. Yet, a few decisive challenges are waiting ahead researchers willing to establish whether or not epigenetics “is the crucial missing piece in the neurotherapeutic puzzle” (Ratan 2009, 976). This is no easy task for the field, since an additional difficulty hindering studies of neuropsychiatric disorders comes from the challenges attached to the collection of the right sample for each study (Urdinguio et al. 2009). The collection of brain samples for Alzheimer's disease or Parkinson's disease is in fact very burdensome for the patient, thus complicating the pathway towards the achievement of tangible therapeutic benefits.

Epigenomics and cancer

By far the most developed sub-field of epigenetic science, cancer epigenetics is an already established set of precious biological insights as well as mainstream clinical applications (Esteller 2007). Recently, the field has moved towards genome-wide approaches, propelled by the availability of next-generation sequencing technologies (Sandoval and Esteller 2012). An important way in which epigenomic techniques have already reshaped our picture of cancer biology regards the elucidation of aberrant DNA methylation patterns at gene promoters. Aberrant DNA methylation has long time ago been associated with tumorigenesis (Feinberg and Vogelstein 1983), due to the alterations it produces on normal gene regulation (Esteller 2007). As reported by Sandoval and Esteller (2012) cancer-related alterations in methylation can be divided into three main subgroups: hypermethylation (Herman and Baylin 2003), hypomethylation (Kulis and Esteller 2010) and loss of imprinting (Sandoval and Esteller 2012). Long lists of hypermethylated genes exist for very different human neoplasias, leading to the conviction that this type of epigenetic alteration ought to be considered the “common hallmark of all types of human cancer” (Esteller 2007, 291). Evidences on different methylation patterns in cancer support the view that, in the near future, each tumour subtype may potentially be assigned a specific "DNA methylome", which could help better define the malignancy, and consequently provide a number of individual diagnostic and prognostic markers for its management.

A paradigmatic example of how this contribution of epigenomics to personalised diagnostics and prognostics of cancer may soon become common practice comes from a review study by Schweiger and colleagues (2013). Here, the authors show how altered DNA methylation patterns have been reported in a diverse array of both preinvasive and invasive cancers, and have already been used for the stratification of patients in clinical subgroups. As argued by the authors, specific alterations in the cytosine methylation patterns of CpG islands in promoter regions are highly predictive as to the concerned tumor entities or stages, and represent a very effective approach to the prediction of cancer formation and progression. Tangible examples of epigenetic prognostics and diagnostics in cancer is provided by the biomarker of hypermethylation for the MLH1 gene (coding for a protein of the DNA mismatch repair machinery), which predicts sensitivity to cisplatin (a chemotherapy drug) in colorectal cancer; or, the biomarker of hypermethylation for the GST P1 gene (coding for an enzyme involved in cellular detoxification), which is highly predictive of proliferation in prostate cancer and a number of additional cancer types (Heyn and Esteller 2012). In comparison to genetic approaches, epigenetic biomarkers display the main advantage of requiring just the analysis of a given gene region (i.e. the CpG island at the promoter *locus*), rather than having to account for a mutational analysis throughout the length of a gene. It is also for this reason that, overall, the clinical value of epigenetic modifications for the identification of biomarkers in cancer tissues can be considered "a technological revolution […] around the corner" (Sandoval and Esteller 2012, 51).

Another important epigenetic player in tumorigenesis is the patterning of modifications to histone proteins. In particular the alterations in histone modification patterns can be explained by two biological events characterising cancer. On the one hand, hypermethylation of CpG islands in tumour cells is known to yield a characteristic combination of histone marks: deacetylation of histones H3 and H4, and gain of H3K9 methylation and H3K27 trimethylation (Esteller 2007). This is mainly due to the fact that a number of proteins involved in DNA methylation (e.g. DNMTs) interact directly with histone-modifying enzymes such as Histone Methyltransferasc (HMT) and Histone Deacethylases (HDACs). For example, DNMTs recruit HDACs leading to histone deacetylation that is commonly associated with transcriptional repression. In addition, methylated DNA strands are also the binding sites for a variety of other proteins, which recruit HDACs as well as other chromatin-remodelers, thus resulting in chromatin compaction and transcriptional inactivation. On the other, an explanation for the role of histone modifications in cancer comes from the analysis of genetic lesions in the *loci* coding for histone-modifying complexes (Sandoval and Esteller 2012). To this second and complementary view, the disruption of patterns of histone modifications in cancer is explained by mutation, deletion and/or altered gene expression of genes encoding for enzymatic components of the epigenetic machinery (Rodriguez-Paredes and Esteller 2011).

Little can be done, to this moment, to reverse the genetic mutations that are inherited in cancer proliferation, and affect protein-coding processes of histone modifiers. Yet, things stand differently in the case of epi-mutations (i.e. the transcriptional regulation of a gene that does not concern the DNA sequence) in histone modifications patterning, which are reversible and hence constitute a promising target for the development of specific compounds. At the basis of this recognition, is the observation that inhibitors of aberrant epigenetic mechanisms display dramatic effects in malignant cells, in comparison to their normal counterparts (Dawson and Kouzarides 2013). This is mainly due to the fact that, under normal cellular conditions, the epigenetic machinery may act together to ensure the achievement of correct chromatin conformation and accessibility, even by devising some semi-redundant mechanisms of interplay among its players (Sandoval and Esteller 2012). Cancer may consequently represent a disruption of this secured concerted activity, actually pertaining only the epigenetic regulation of a few pivotal target genes, thus rendering "a slight tip in the balance of this regulation […] sufficient to result in a cell catastrophe" (Dawson and Kouzarides 2012, 23). Otherwise stated, cancer cells may in many respect display an ‘epigenetic vulnerability’ that opens up numerous possibilities for therapeutic intervention. Some cancer cells are reliant on specific epigenetic pathways, whereas normal cells have alternative compensating pathways to rely on. This recognition has led to a huge effort in the quest for epigenetic drugs, which has already brought about some tangible clinical results. Among the compounds that target epigenetic processes, the most extensively studied are inhibitors of DNMTs and HDAC, which (as reported above) have already reached mainstream oncology both in Europe and the US (Damjanovicova, *unpublished results*).

Taken together, these evidences from epigenomics support many of the hypotheses concerning the molecular roots of cancer, but they also challenge some others. Although it is still commonly held that cancer is a disease fundamentally driven by genetic anomalies, it is now clear that epigenetic pathways should not be underestimated as to their role in oncogenesis (Dawson and Kouzarides 2012). In fact, little doubt exists that some of the hallmarks of cancer, such as malignant self-renewal, differentiation blockade, evasion of cell death, and tissue invasiveness are deeply determined by changes in the epigenome (Esteller 2007). However, the major rewriting of the biography of cancer that epigenomics has just begun, concerns a rather different theoretical shift in the understanding of its aberrant biology. Differently from cancer genomics, emphasizing the potential of sequencing for the identification of relatively few and well-defined genetic alterations at the basis of the disease, epigenomics brings into the picture of the molecular understanding of cancer complexity, stochasticity and environmental interactions as key elements of its biology (Bock 2009). Epigenetic alterations not only complement the widely acknowledged role of genetic alterations in tumours, but also purport to finally embrace and unveil the complex tapestry of underlying molecular events that administer the development of cancer processes. The combination and integration of high-resolution epigenome mapping technologies with genomics all the other ‘omics promises, in other words, to identify the set of individual predispositions, lifestyle behaviours, environmental cues that are reflected in particular cancer signatures, thus constituting a new and exciting prognostic, diagnostic and therapeutic tool in the personalization of cancer care (Sandoval and Esteller 2012).

Conclusions

The present analysis of the impact of epigenomics on Personalised Medicine (PM) shows that the interest in epigenetic phenomena – notwithstanding their blurred boundaries – has experienced an exponential growth over the past few years. Currently, epigenetic mechanisms are regarded as an integral part of our understanding for several common human diseases, such as cardiovascular diseases, neuropsychiatric disorders and cancer (World Health Organization 2010). With regard to these important domains of healthcare, we have seen how epigenomics promises to elucidate the relationship between genetic and (some) non-genetic determinants of complex diseases, and to progress our understanding of the multi-factorial nature of disease development. In a nutshell, epigenomics may finally put the genotype *into the context* of the myriad of environmental triggers (broadly understood) that contribute to any phenotype, and have long-lasting consequences for individual health.

Beyond the details of this fascinating endeavour, it is now important to recapitulate how this aspect of epigenomics has a fundamental bearing on the project of PM. Going beyond the rhetoric of PM that "starts with the patient" (European Commission 2013, 6), evidence from epigenomic studies suggests a unifying molecular language for both biographical and biological marks, which – I shall say – *stays* with the patient throughout the whole lifespan. From lifestyle behaviours and environmental pollutants, to stress reactions and cognitive functions, epigenomics promises – and has already started – to provide a unified digital heuristics (Meloni and Testa 2014) for measuring the complex interactions in health and disease. In doing so, epigenomics plunges into – and lumps together – the unique combination among these factors at the basis of individual illness. This represents a fundamental shift in the ontologies of both disease aetiology and health outcomes, and also a monumental leap forward in the implementation of the project of PM. The stratification of patients based on their multiple and evolving epigenomic profiles (Costa 2010) may become in fact the best way to subgroup patients, and to optimize preventive and therapeutic care on the specificities (both social *and* biological) of each individual. As showed above, epigenomics may soon provide us with an outlook of how social forces, such as socio-economic status and environmental exposures, get embodied with consequences for adult cardiovascular risks and health (McGuinness et al. 2012). In addition, we have also seen how these groundbreaking discoveries open up huge opportunities for the development of tailored and personalised therapies. Epigenomics has already begun to radically change the approach of pharmaceutical companies to the identification and testing of new cancer drugs, and will most likely extend its influence over other domains of healthcare. The idea of a blockbuster drug that could treat a broad spectrum of tumour types has become even less likely after the advent of epigenomics. Cancer is a complex disease, and even a specific cancer type has a variety of subclasses, or specificities, with completely different pathological and molecular features, which could be captured (also) by epigenomics maps (Costa 2010). These recognitions point to a unique role played by epigenomics in PM, since it can help in the identification of groups of patients with the same epigenetic changes – being them life experiences, or environmental exposures – shaping the characteristics of their medical conditions.

And yet, as we will see in the next chapter, there is more to epigenomics than just providing a molecular gaze on individual aetiology of complex diseases (Nowotny and Testa 2011). The recent developments in the field reviewed above, assign in fact a rather different (and complementary) role to epigenomics in the public unfolding of PM. As elegantly put by Meloni and Testa:

> this openness to the environment, in its broadest sense, invites [also] the expectation of change, the notion that once the genome has been downgraded from the high citadel of causal primacy, to the messy roundabouts of reactive developmental resources, biological fates become inherently reversible and porous to intervention" (Meloni and Testa 2014, 13-14).

To this view, what is worth noting about emerging epigenomic healthcare is its alignment with the new "sociotechnical imaginary" (Jasanoff and Kim 2009, Jasanoff and Kim 2013) of individualized, environmentally situated and empowering medicine problematized throughout this work. Epigenomics is already entering the public arena as a resource for reconfiguring individual and collective *responsibilities* for health (Hedlund 2012, Chadwick and O'Connor 2013), be they inflected as a demand of accountability for damaging one's epigenetic makeup (due to lifestyle, environmental exposures, etc.), or as a prospective responsibility to act upon this information and improve one's own epigenome (Meloni and Testa 2014).

There is, in other words, a dark side of the promise of epigenomics to make increasingly visible the 'contextual nature' of health (Landecker and Panofsky 2013, Meloni and Testa 2014), and its potential to fuel the power of post-genomic narratives to provide "the right therapeutic strategy for the right person at the right time" (European Commission 2013, 5). By illuminating biological mechanisms underlying the interaction between lifestyle, living conditions and individual health, epigenomics should not be regarded as merely providing a "bio-dosimeter" (Landecker and Panofsky 2013) of the social and environmental influences inherently affecting individual health. Rather, epigenomics is best understood as partaking to the constitution of the *patient citizenship* project criticised throughout this work, which integrates knowledge of our somatic individuality (this time at the crossroad of biological, environmental and behavioural factors, and not only genetic) with moral and political claims of individual responsibility and empowerment to protect our epigenome from external aberrant influences.

This recognition calls for abandoning the narrow view of the epigenetic discourse as a mere configuration of molecular knowledge on social phenomenas and their impact over health (Landecker and Panofsky 2013). Rather, this view calls for embark upon the scrutiny of the potential tensions generated by epigenomics' *promise and demand* of intervention upon one's health vulnerabilities. Once we recognise that epigenomics may be a major driver for the political constitution of the 'empowering PM' scrutinized in this work, it automatically becomes a promising terrain to put to test the normative theorization of empowerment resulting from Part 1. For this reason, in the remaining of this work, epigenomics will be addressed as one of the pillars of the social and political program of EBRs, where its *representation* of complex social phenomena (such as the adverse social conditions to which we are exposed) in the molecular language of DNA methylation, histone modifications and RNA-chromatin interactions, gets translated into the allegedly *empowering* normative dimension of responsibility to reshape one's epigenetic biology.

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Chapter 7. The epigenomic hype: between responsibility and empowerment

Introduction

As argued in Chapter 6, investigating the *plasticity* of our epigenomes to environmental triggers can mobilize a narrative of individual responsibility with regard to health and diseases (Meloni and Testa 2014). Epigenomics promises in fact to illuminate the interplay between genetic and non-genetic determinants of health, with a significant impact on our understanding and *personalised* management of complex diseases (Rakyan et al. 2011). In particular, we have seen how next-generation sequencing techniques for epigenomic analysis promise to make increasingly *visible* (Nowotny and Testa 2011) the biological mechanisms underlying the interaction between lifestyle, living conditions and individual health. In this respect, I concluded, the flip side of unveiling the 'molecular conduit' (Landecker and Panofsky 2013) that adapts the epigenome to environmental exposures is the rise of expectations to safeguard its vulnerability from the assaults of lifestyles, occupational exposures, pollution, parental care, etc. Indeed, epigenomics has already been cast in terms of posing an additional responsibility for the management of individual health (Hedlund 2012, Rothstein 2013, Chadwick and O'Connor 2013, Loi et al. 2013). Once molecular knowledge of the impact of lifestyle and environment on disease aetiology becomes available, this line of reasoning goes, one expectation is that individuals may be held liable for the consequences of their health-related and epigenetically accountable decisions.

In this chapter, I build upon this notion of 'epigenetic responsibility' and problematize the emphasis on individual responsibility from the empowerment perspective defended in Part 1. To do so, I start from a reconstruction of the main arguments in favour, or against the legitimacy of normative claims of 'epigenetic responsibility' (Hedlund 2012, Rothstein 2013, Chadwick and O'Connor 2013). With regard to this matter, I show that these normative appraisals of epigenetic responsibility build upon the already existing debate on responsibility for health analysed in Chapter 4. Accordingly, I show how claims of 'epigenetic responsibility' can be addressed both on the basis of arguments (Morreim 1995, Cappelen and Norheim 2005, Feiring 2008, Segall 2009, Voigt 2013) and counter-arguments (Minkler 1999, Wilkinson 1999, Buyx and Prainsack 2012, Brown 2013) for moral responsibility in public health ethics. Then, I move to a discussion of the idea that epigenetics reinforces ascriptions of liability for environmental and lifestyle exposures. I suggest that, whether this is the case, depends on the standards of evidence in epigenetic medicine. Namely, I argue that holding individuals responsible for aberrant epigenetic modifications depends also on the degree of analytic validity, clinical validity and clinical utility of epigenetic knowledge (Mill and Heijmans 2013). Whether epigenomics will become pivotal in orienting agency across a range of responsible healthy options is in fact conditional to the definition of the epistemic status of epigenomic profiles and their actionability with respect to the health-related impact of environmental and lifestyle exposures.

Finally, I turn to an evaluation of claims of epigenetic responsibility on the basis of my normative account of empowerment. On the one hand, I argue that the premises of empowerment point to the difficulties of solving these matters by trading off individual merit and possible sanctions for health-related behaviours. In contrast to the individualisation of social policy currently dominating healthcare (Shapiro 2012), the perspective I proposed requires in fact approaching normative matters of liability and accountability in healthcare (including the ones based on epigenetic medicine) by taking up the inherently *ecological* (Minkler 1999) nature of moral and legal responsibility for one's behaviour. This means that an empowerment approach to epigenetic responsibility affirms the need to refrain from attributions of liability for epigenetic scars (i.e. aberrant epigenetic modifications) at the individual level (Hedlund 2012, Chadwick and O'Connor 2013).

On the other hand, I maintain that the promise of epigenomics to make increasingly visible the interaction between lifestyle, living conditions and individual health (see *infra* Chapter 6), should not limit its societal appraisal to the danger of burdening individual responsibility for health. Rather, I argue that epigenetic knowledge may become pivotal in fleshing out social and environmental influences inherently affecting health-related agency. From the perspective I develop here, epigenetic knowledge about social, environmental and lifestyle exposures determining health may in fact guide individuals across the spectrum of social determinants of one's health (Marmot and Wilkinson 2003, World Health Organization 2013), thus championing epigenomics with the potential of serving the *empowering* aims fleshed out throughout this work.

There is, in other words, a two-way conceptual movement linking the political project of an empowered citizenship in healthcare, and the societal unfolding of epigenomics. The possibility I explore here is that empowerment and epigenomics may respectively shape their own political and epistemic dimensions in the future of healthcare. On the one hand, the normative resources of empowerment I developed in this work may prevent inflated claims of moral responsibility for epigenetic damage of one's health. On the other, the promise of epigenomics to annotate the systematic health disadvantage in our society (in the form of a molecular read-out of the health-related consequences of one's exposures and lifestyles) bestows to this technology the potential to empower citizens' agency across the myriad of social and contextual determinants of one's health. It is thus towards the identification of the possible synergies between these two promising tropes of contemporary healthcare that the final remarks of this work will be devoted.

Normative claims of personal epigenetic responsibility for health

The main reason why epigenomics has been linked to normative matters of social and individual responsibility for health is the molecular gaze it sheds on the biological mechanisms linking environmental factors and genes (Rothstein et al. 2009a, 2009b). As shown in Chapter 6, epigenetic research has a number of potential applications in Personalised Medicine (PM), and bears the promise of clarifying the relationship between lifestyles, living conditions, health and wellbeing. As a result, epigenomics enables individuals and societal institutions to act accordingly to this knowledge, but also to do otherwise (Hedlund 2012). It is starting from these features of epigenomics that responsibility concerns arise, as to whom should be held liable – between the individual and the wider society – to "do something" (Chadwick and O'Connor 2013, 464) about this knowledge. In particular, it is worth noting here how arguments in favour of epigenetic responsibility build upon the well-established emphasis on responsibility for lifestyle behaviours and health outcomes in the ethics of public health (see *infra* Chapter 4).

The avenues to construct arguments in favour of responsibility to protect one's epigenome and health can, in other words, be identified among the normative resources previously discussed in this thesis (see *infra* Chapter 4). And indeed, building upon the distinction between backward- and forward-looking accounts, some scholars have already argued that, as epigenetic damage may be brought about by voluntary conduct (such as smoking or diet), individuals must bear – both retrospectively and prospectively – the responsibility for this damage (Wiener 2010, Hedlund 2012, Chadwick and O'Connor 2013). In particular, the taxonomy of arguments I presented in Chapter 4 can help us identify how different normative accounts would specify this general argument in favour of epigenetic responsibility in different ways.

Certainly, one could imagine how a luck egalitarian approach (Segall 2009, Voigt 2013) would support claims of backward-looking epigenetic responsibility for health. Recall that this theory stipulates health inequalities to be "fair if and only if they are the result of choices for which agents can be held responsible" (Voigt 2013, 147). For this reason, it is easy to imagine that a luck egalitarian would argue that, since many epigenetic aberrations are the result of individual choice and behaviour, we do not have reasons of justice to include treatment of the resulting health conditions in the provision of publicly funded healthcare services. At the same time, a second kind of appeal to epigenetic responsibility based on its backward-looking understanding could be derived from the normative perspective of liberal egalitarians (Cappelen and Norheim 2005). Remember that while luck egalitarians consider individual choice sufficient ground to ascribe her the burden of their consequences, liberal egalitarians draw a distinction between choices and consequences that has strong normative relevance. To hold people responsible for the actual consequences of their choices is in fact too extreme for the liberal egalitarian, because the outcomes of individual choices depend also on other factors. This is a particularly poignant consideration in the normative appraisal of epigenetic responsibility, because some of these mechanisms are also stochastically disrupted (Feinberg 2014). For this reason, the liberal egalitarian would say that the health-related consequences of epigenetically unhealthy habits can partly be regarded as luck for which compensation is deemed legitimate (Cappelen and Norheim 2005). Accordingly, one could play out this main difference between luck and liberal egalitarians, by pointing out how epigenetic responsibility should be allocated on *choices* (through mechanisms that reward epigenetically healthy behaviours or penalize unhealthy ones), rather than health-related *consequences*.

The same goes for claims of responsibility for health based on its 'forward-looking' interpretation. In its liberal-contractualist declension (Feiring 2008), this line of reasoning would claim that whether a subject is given an epigenetic information (such as 'action X' may bring about the epigenetic aberration 'Y'), and she decides to sign an imaginary contract declaring a commitment to undertake activities aimed at avoiding Y, she could be held responsible for ignoring the advice (Chadwick and O'Connor 2013). Furthermore, and from a utilitarian perspective (Morreim 1995), it could be argued that inculcating epigenetic responsibility for health, through a system of economic incentives, may encourage behaviours that maximise health and wellbeing in the population. By making epigenetically *hazardous* lifestyles less appealing for citizens these incentives may in fact reduce costs of treatments for certain conditions, and at the same time maximise instances of appropriate and healthy choices.

Assessing normative claims of epigenetic responsibility for health

In reply to these different lines of reasoning on individual epigenetic responsibility for health, it is possible to identify a number of considerations, which challenge the validity of such normative claims. Besides "playing the cards" of normative arguments against attributions of responsibility for health identified in Chapter 4, this section questions the notion of 'epigenetic responsibility' also on different grounds. First, I show how the epistemic validity and utility of the epigenetic knowledge on common diseases is still in its infancy, and how this recognition challenges the widely held belief (Hedlund 2012, Chadwick and O'Connor 2013) that molecular knowledge of the impact of one's lifestyle over health *strengthens* the legitimacy of normative claims of responsibility. Second, I also approach another largely underestimated aspect of this debate. Namely, I question the epistemic premises behind the emphasis on 'epigenetic responsibility' as a distinct ethical issue of epigenomics rather than genomics (Rothstein et al. 2009a, 2009b, Chadwick and O'Connor 2013, Rothstein 2013). This view, I show, simply forgets the numerous ways these two fields intertwine (Meloni and Testa 2014) and runs the risk of obfuscating their important synergies in the constitutional project of the 'empowered patient citizenship' problematized throughout this work.

Claims against epigenetic responsibility for health

Besides arguments in favour of epigenetic responsibility, also a number of counter-arguments can be isolated from debates in public health ethics. As we will see in this section, most of these lines of reasoning question the struggle to isolate an actor to hold responsible for epigenetic aberrations. One way of carrying out this task is to point out that not everyone is well-equipped to understand, manage and act upon risk of epigenetic damage, and that inculcating responsibility may therefore disadvantage those who cannot take advantage of relevant epigenetic knowledge (Hedlund 2012, Chadwick and O'Connor 2013). In essence, these are the same points we already encountered in public health debate about the barriers to individual *freedom* in making lifestyle decisions (Brown 2013). According to this view, appeals to epigenetic responsibility for health would be morally problematic because they conflate causal responsibility for disease aetiology with moral claims of responsible agency for unhealthy behaviours. Although it is impossible to deny that as individuals we have a fundamental influence on our health, it is far from clear – according to this view – whether we are sufficiently *free* in doing so, and consequently whether we should be held responsible for our epigenetically accountable actions. Socioeconomic status and background can be consistently shown to impinge upon our freedom as a condition to act responsibly (Pettit

2001), and therefore we should reject claims of responsibility also with regard to the safeguard of our epigenome. In addition, and specifically to matters of epigenetic responsibility, this line of reasoning would also point to the difficulties of understanding the molecular information of epigenomics. From such a perspective, not every citizen may be sufficiently able to grasp, manage and act upon epigenomic information as to one's health risks, and – for this reason – insisting on epigenetic responsibility may be problematic due to the potential consequences it could yield for the most disadvantaged groups of our societies. Only those who are free and already better off would benefit from the potential of epigenomics to improve health-related decision-making.

Alternatively to freedom-based rebuttals, also appeals to solidarity may provide normative grounds to reject claims of epigenetic responsibility (Buyx and Prainsack 2012). Building upon this recent shift in applied ethics, one could identify a number of weaknesses in the arguments played out above. First, a solidarity-based approach would point out that an excessive emphasis on individual responsibility for one's epigenetically acquired aberrant traits fails to live up to solidarity-based social norms and structures (e.g. welfare systems and social welfare arrangements) that represent an explicit commitment to attend to vulnerabilities of other members of society (Buyx and Prainsack 2012). Even though the attribution of epigenetic responsibility may be a valuable strategy to promote general wellbeing and to optimize the use of healthcare resources, over-stating its importance overlooks other values founding our collective life, i.e. the ones comprised by the notion of solidarity.

Second, this line of reasoning would also insist upon the difficulties in pinpointing the alleged *causal* link between individual behaviour, an epigenetic scar and the resulting health condition (Buyx and Prainsack 2012). As shown in Chapter 4, solidarity scholars question the possibility to ground allegations of moral responsibility on the causal responsibility the individual has with regard to a particular (health) outcome. In the view they criticize, distributing responsibility means first of all ascertaining that the individual has *causally* produced a state of affairs, and then evaluating whether this action deserves an ascription of fault, praise or blame (Miller 2001). The problem with this account is, however, that behaviours are only *part* of the causes of lifestyle-related diseases. Indeed, these conditions are thoroughly multifactorial and include environmental influences, individual biological make-up and lifestyles alike. Hence, since we are not in the *epistemic condition* of disentangling the contribution of each of these factors, we should dismiss claims of responsibility in healthcare.

This general consideration of solidarity scholars is likely to play an important role in the discussion of normative matters of epigenetic responsibility. On the one hand, one could argue that the main promise of epigenomics is precisely illuminating how these different factors interact (genome-wide) to bring about a given health outcome (Wiener 2010). In this respect, epigenomics could potentially provide solid ground to claims of causal responsibility questioned by solidarity scholars, hence discarding their critique of these appeals to responsibility for health. As we have seen in Chapter 6, the idea of a life-long epigenetic read-out (mapping the continuous plastic modifications of the epigenome to environmental and lifestyle exposures) *could* disembroil the different contribution that all kinds of factors bring to the development of a condition. For instance, we have noted how a new conceptual model for the understanding of disease aetiology of CVDs emerges from epigenetics (Baccarelli et al. 2010), which might help to explain how environmental and lifestyle factors respectively impose aberrant and individually unique gene expression patterns in an individual's lifetime.

On the other hand, one could also point out that it is debated whether or not epigenomics will extricate these interactions, and that this recognition should count in the evaluation of normative claims of epigenetic responsibility. This line of reasoning would emphasize that the more we plunge into the epigenetically mediated interaction between lifestyles, environmental exposures and genetic background the more we note how the boundaries between these three players get fundamentally *blurred* (Meloni and Testa 2014). The molecular and integrative language of the epigenome obfuscates – rather than illuminates – the border between what counts as genetic or lifestyle- and/or environmentally-induced effect, or even between what is nature and what is nurture (Landecker and Panofsky 2013, Meloni and Testa 2014). According to this view, assessing the contribution of each of these factors to our epigenome-patterning becomes therefore not only an unanswerable question that jeopardizes claims of causal responsibility – like solidarity scholars think (Buyx and Prainsack 2012) – but also an underestimation of the holistic explanatory power of epigenome maps. Rather than striving to isolate an actor to be held responsible for *each* aberrant epigenetic influence, endorsing this view leans towards investigating the value of this knowledge in the appreciation of the structural factors (from genetic, to behavioural and environmental ones) that *together* shape our health. An epistemic question that seems decisive in establishing whether claims of responsibility acquire a new force through epigenetic knowledge.

Does state-of the-art epigenetic knowledge strengthen normative claims of responsibility for health?

To this stage of the present analysis, advances in epigenomics do not represent "any changes in kind" (Hedlund 2012, 178) with regard to existing normative matters of responsibility in the public health ethics literature. As we have seen above, these matters can in fact be addressed by resorting to existing general arguments on individual responsibility for health. Yet, most of the authors debating epigenetic responsibility are convinced that this knowledge does "make a change in degree" in resolving general ascriptions of responsibility for health same arguments (Hedlund 2012, 178). According to this view, apportioning responsibility through epigenomics arguably acquires an epistemic status, which is rather different from the one of the epidemiological data on which this debate originally grows out (Rothstein et al. 2009a, 2009b). Rather than pointing to the *association* of a given behaviour (e.g. unhealthy eating) and a relevant health outcome (e.g. cardio-vascular diseases), epigenomics is bestowed the potential to provide a precise knowledge of the *molecular* chain of events (or 'conduit'; see Landecker and Panofsky 2013) that starts from a certain lifestyle- and/or environmentally-related factor (e.g. a nutrient like fatty acid) and causally leads to disease development. And for this reason, different scholars agree that arguments in favour of allegations of personal responsibility for health acquire, through the language of epigenomics, a whole new strength (Hedlund 2012, Chadwick and O'Connor 2013). This epigenetic information, they argue, has "significant implications for the extent to which people are in a position to make a choice about the kind of life they want to live" (Chadwick and O'Connor 2013, 465).

This recognition deserves at least to be problematized. It is in fact very common in contemporary biomedicine to interpret new discoveries as challenging, or blurring the distinction between knowledge and its application. As argued by Nowotny and Testa (2011), casting a molecular glance to the understanding of human diseases, has had the effect of transforming knowledge-production into action. In one sentence: "understanding life means changing life" (Nowotny and Testa 2011, 5): a conceptual move which is not neutral from a moral standpoint. Once we illuminate the molecular conduit (Landecker and Panfosky 2013) from nutrients, through the epigenome, to cardiovascular disease risk (just to give an example), we inaugurate (or most likely tip the balance in already existing) normative discourses about values and expectations. Knowing what is the effect of our dietary habits on our epigenome, and consequently on our health, fortifies options of "*what ought to be*" done to protect its integrity (Nowotny and Testa 2011, 6).

Yet, a decade of genomics should have probably taught us to be careful in concluding that higher quantity of molecular information regarding our biological make-up automatically results in improved quality of decisions (i.e. capacity, or opportunity to make better decisions) with regard to our health (Caulfield et al. 2009). What seems to be absent from debates on epigenetic responsibility is, in other words, an appreciation of all the conditions under which this knowledge qualifies as valid, reliable and actionable knowledge to improve one's health (Mill and Heijmans 2013). Besides the question above-mentioned as to whether epigenomics will allow discriminating between different factors of disease aetiology, another open question here is whether this knowledge is sufficiently valid and useful so as to better orient agency. Like any biological test used in medical practice, also epigenome-based analyses, which are currently under development (see *infra* Chapter 6), will have to be evaluated in three main respects before translating into concrete possibilities and benefits to citizens (Hunter et al. 2008). This means that epigenomics ought necessarily to comply with a number of already-existing criteria for the validation of medical information, before considering this knowledge as having a concrete impact upon individual behaviour and responsibility.

First, it is still unclear whether epigenome-based analysis fares good with regard to its *analytic validity* (i.e. the capacity of a test to detect a given trait). Epigenetic landscapes are in fact tissue-specific and this may have an effect over the sensitivity and specificity of epigenetic testing. Differently from genetic variables (e.g. single nucleotide polymorphisms), which potentially (albeit still limitedly) can be identified in all possible cells of the human body, epigenetic analyses suffer from the difficulty of assuming that the effect of a given marker (e.g. DNA methylation) is detectable in easily accessible surrogate tissues, or in a tissue which is different from the one relevant to the condition under study. This means that, since each specialized type of cell is expected to have different epigenetic profiles, a change in the epigenetic pattern linked to a condition may be difficult to detect in the available cell type, such as (most typically) blood (Jones and Liang 2012). Despite this complication, a widespread consensus can be currently found in the scientific community as to the importance of addressing this main limitation of epigenetic studies, and indeed a number of studies have already focused on the identification of common epigenetic patterns across different cell types (Michels 2012).

Besides the reservations arising from the tissue-specificity of epigenetic profiles, it is worth taking into account another limitation for the current biological significance of epigenetic knowledge. It is in fact far from clear that the information gathered from the available tissue (e.g. peripheral blood) may meet standards of *clinical validity* (i.e. the capacity of a test to diagnose a condition and predict an outcome). Investigating the epigenome is supposed to detect specific features of disease aetiology (e.g. the impact of DNA methylation on tumour prognosis) before counting as relevant risk-profiling or diagnostic test for individual patients. Unfortunately, most of these studies are currently still based on correlative analyses, which question their capacity to detect these conditions adequately (Mill and Heijmans 2013). Even though measurements of epigenetic associations are "strongly suggestive of being causal" and can "provide clues about underlying mechanisms", the functional consequences of these changes are "not yet understood" (Mill and Heijmans 2013, 589). These associations have higher or lower credibility that question their predictive value, especially because of the limitations inherent in the available technologies for quantification of epigenetic modifications (Mill and Heijmans 2013).

Finally, another set of difficulties identifiable in current standards of epigenetic knowledge relates to their *clinical utility* (i.e. the cost-benefit analysis of introducing a particular test in clinical practice). Specifically this criterion points to the necessity of estimating, before using epigenomic information in public health, that such information predicts disease risk better than other phenotypic biomarkers; that cost-effective interventions exist for those at increased risk; and that epigenetic risk information is sufficiently actionable to motivate changes of behaviour for the concerned individual. Otherwise stated, a number of questions may need to be answered before giving free reign to epigenetic knowledge in directing and delineating individual responsibility for one's health: does this information allow treating the condition likely to be developed? If so, is it likely that people act on the grounds of the knowledge acquired via the test? Has the trade-off between the psychological impact of the test and the possible advantages of the knowledge produced, been assessed?

It seems that most of the available knowledge on the epigenetic roots of common diseases fails with regard to these fairly reasonable objectives (Mill and Heijmans 2013). This is not meant to deny the important *promises* and hopes that epigenomics may most likely bring to the future of medicine (see *infra* Chapter 6). The point here is a rather different one. Namely, the analysis above shows that the impact of epigenomics on the notion of personal responsibility for health demands taking such knowledge with a grain of salt rather than subscribing to the "socio-technical hypes" and consequent expectations it may produce (Meloni and Testa 2014, 6). Epigenomics promises to replace knowledge of the *association* between one's lifestyle or environmental exposures and health outcomes, with a fine-grained appreciation of the *molecular* effects of these influences on our body. And yet, this can hardly be regarded as automatically urging us to act upon this knowledge. Whether or not epigenomics makes "a change in degree" (Hedlund 2012, 178) for normative claims of responsibility to protect one's epigenome and health depends rather on its capacity to provide a reliable, valid and actionable set of knowledge about health-related molecular effects of one's behaviour or environmental conditions. This means that the value of epigenomics information in guiding individual behaviour, responsibility and decision-making will very much depend on its capacity to comply with the already established standards of analytic validity, clinical validity and clinical utility discussed in this section of my work.

Why does responsibility matter for epigenomics more than genomics?

Finally, there is another issue attached to the notion of epigenetic responsibility, as it is currently debated in the philosophical and sociological literature (Rothstein et al. 2009a, 2009b, Hedlund 2012, Rothstein 2013). The emphasis on normative matters of epigenetic responsibility grows out of the search for specificities in the societal impact of epigenomics *vis à vis* that of genomics. Many authors agree that a foundational issue in determining the ethical, legal and social implications (ELSI) of epigenomics regards an appreciation of whether challenges raised by epigenomics differ from those of genetics and genomics (Rothstein et al. 2009a, 2009b, Chadwick and O'Connor 2013, Rothstein 2013). Answering this question, they argue, means looking at the current biomedical literature on epigenomics, and then identifying in what respects this endeavour differs from genomics in an ethically, legally and/or socially relevant manner.

In general, this line of reasoning builds upon the recognition that epigenomics unveils *the* missing link between one's genetic endowment and the number of environmental stimuli that determine health and disease. Epigenomics, these scholars argue, can illuminate – differently from genomics – the early-life events that cause an epigenetic drift in one's susceptibility to diseases (e.g. the Dutch hunger famine discussed in Chapter 6; see Heijmans et al. 2008), and the fundamental contribution of environmental and social mediation to one's health (e.g. the bio-dosimeter of health inequalities in Glasgow analysed in Chapter 6; see McGuinness et al. 2012). Furthermore, and again in difference from genomics, epigenomics unveils the malleability and plasticity of our biological make-up with respect to all of these exposures, as well as the potential reversibility of their effects (Landecker and Panofsky 2013). It is therefore the fact that epigenetic traits are susceptible to *intervention* (e.g. changes in lifestyles and/or environmental exposures), which posits – for these authors – ethical questions about responsibility for ameliorating one's epigenetic risks that do not pertain to genetic medicine (Rothstein et al. 2009a, 2009b, Hedlund 2012, Rothstein 2013).

With regard to this view, I maintain that it is undoubted that the information gained through epigenomics evokes an imaginary of direct applications that, in contrast to genomics, appears to fall *within everyone's means*. Epigenomics makes visible, in a molecular language, the effects that one's unhealthy habits have over health. In doing so, it provides relevant information that can be *prima facie* enacted more easily than knowledge of one's genetic susceptibilities. Changing one's lifestyle is in fact within everyone's range of possibilities: a line of reasoning that does not apply to 'changing the genes we are born with', or acting upon one's genetic susceptibilities (Hedlund 2012). An important reason why 'genetic responsibility arguments' have rarely been proposed is, in other words, that no effective action can be taken to *eliminate* genetic risks (Resnik 2014). Besides continuing health monitoring, or the very recent progresses in gene therapy for a limited number of conditions (Aiuti et al. 2013), or the limited preventative measures available for some conditions (e.g. radical pre-emptive surgery to remove the risk of developing breast associated to BRCA1 aberrant mutations), very little possibilities of intervention exist for a genetic condition. Things stand differently, however, if we analyse claims of 'epigenetic responsibility'. The plasticity and reversibility of epigenetic traits gets often interpreted as subverting the view ascribing to the genome the status of an intangible inherited set of biological predispositions. The epigenome is regarded as a digital representation of many activities that fall within individual control and points to the adoption of lifestyle-related changes to eradicate the source of epigenetic risk for which responsibility is evoked (Meloni and Testa 2014). In a nutshell, epigenomics differs from genomics because it opens up for increasing control over the environmental factors interacting with genes, and illuminates the extent to which an actor can make an influence over the aberrant drifts these interactions can bring about. Hence, it is for this reason that matters of individual responsibility are more likely to *be given* a higher relevance in the societal appraisal of epigenomics, than the one they were given in the case of genomics (Chadwick and O'Connor 2013). What needs to be clarified in this view, however, is why knowledge of the internal (to the organism) mechanisms of reaction to environmental stimuli improves the opportunities for control outside the organism.

Besides this concern, this view runs the risk of overlooking at least two important considerations. First, it is unclear whether it is feasible to hold epigenomics and genomics as two separated endeavours like most of these scholars propose (Chadwick and O'Connor 2013, Rothstein 2013). The view they endorse, according to which epigenomics parallels genomics in the production of societal and ethical challenges, simply forgets the numerous ways in which these two fields intertwine (Meloni and Testa 2014). On the one hand, we have already seen how difficult it is to draw a line in the definition of what counts as epigenetic and what counts as genetic (see *infra* Chapter 6). On the other, epigenetics is not a way to investigate the aetiological quandaries of most common diseases affecting human health that is *alternative* to genetics. Rather, it is a quantum leap in the study of human diseases inaugurated and reinforced by a decade of genomic research and medicine (see *infra* Chapter 6). In this respect, the epistemic premises behind the emphasis on 'epigenetic responsibility' as an ethical issue of epigenomics rather than genomics, are much more nuanced than most of these scholars believe. Identifying challenges of responsibility as solely a consequence of epigenetics means, in a nutshell, overlooking the multiple interconnections between these two endeavours (Meloni and Testa 2014).

Second, it seems odd to claim that epigenomics actually imports the discourse of responsibility for health into contemporary molecular medicine. An increasing attention is in fact currently paid also to the idea that we should be held responsible for addressing our genetic risks (Resnik 2014). From genetic testing and preventative measures for genetic predispositions, to pre-natal diagnostic or screening techniques (e.g. amniocentesis, chorionic villus sampling, enrichment of fetal cells from maternal blood), a number of scholars have already pointed out how genetics impacts on the notion of responsibility for both one's health

(Resnik 2014) and that of future generations (Wilkinson 2010). Under this interpretation, epigenomics does not pose a *novel and molecularized* ethical demand to act responsibly in order to ameliorate one's health risks. Rather, it may only "succeed" in dismissing what genetic medicine has already started to challenge: namely, the idea that we cannot control the genes we are born with (Meloni and Testa 2014). On the one hand, through genomics we are called upon acting responsibly to control the health-related impact of our genetic risks, by undergoing continuing health monitoring or adopting the preventative measures available for some conditions (e.g. radical pre-emptive surgery to remove the risk of developing breast associated to BRCA1 aberrant mutations). On the other, the contribution of epigenomics to normative matters of responsibility demands protecting one's genome from the numerous external assaults to its healthy functioning, by changing one's lifestyle or environmental exposures.

The view I propose here challenges therefore the widely held belief that epigenomics gives rise to a unique emphasis upon normative questions of responsibility. If responsibility matters in the societal appraisal of epigenomics is not because, as most scholars believe (Rothstein et al. 2009a, 2009b, Hedlund 2012, Rothstein 2013), epigenetic science differs from genetics in this ethically relevant manner. Quite the contrary, epigenomics should be regarded as moving ahead the reconfiguration of personal responsibility for one's health to which genomic medicine has already contributed. By expanding the possibilities and domains of agency where such normative claims can be directed, epigenomics is no more than reinforcing a much broader discourse of responsibility to act as stewards of our health (or to even prevent harms to future generation), leveraged by molecular knowledge of our (epi)genetic individuality (Rose and Novas 2005). In one sentence, claims of responsibility to protect our epigenomes should be addressed as a fundamental part of the constitutional project of the 'empowered patient citizenship' problematized throughout this work.

Interim Conclusions

All of these thoughts combined provide us reasons to question apportions of either causal or moral responsibility to individuals for particular epigenetic changes. Beyond the issue of ascribing freedom of choice to individuals in making epigenetically aberrant decisions (Brown 2013), another problem regards the emphasis put on individual responsibility, which overlooks the importance of socially robust practices of solidarity in our collective life (Buyx and Prainsack 2012). In addition, another set of problems identifiable in the notion of epigenetic responsibility deals with the troubles of explaining how lifestyles alone causally affect the epigenome. This recognition should rather be countered with the possibility that epigenomics may actually flatten the differences among factors (from genetic, to behavioural and environmental ones) of disease aetiology in a unique holistic language that quantifies how *together* they shape our health (Meloni and Testa 2014).

In addition, I also questioned the idea that normative claims of epigenetic responsibility "make a change in degree" (Hedlund 2012, 178) in comparison to the same kinds of issues in public health ethics. With regard to this, I showed that unless epigenomics provides a reliable, accessible and actionable set of knowledge about the molecular effects of one's behaviour or environmental conditions, this alleged "change in degree" has very little ground and resembles more a "socio-technical hype" (Meloni and Testa 2014, 6), rather than a cogent enhancement of "choice about the kind of life [people] want to live" (Chadwick and O'Connor 2013, 465).

Finally, I also turned to the overlapping consensus (Rothstein et al. 2009a, 2009b, Chadwick and O'Connor 2013, Rothstein 2013) as to the specificity of issues of responsibility in epigenomics, as opposed to those raised by genomics. As to this matter, I proposed that we have reasons to believe that epigenetic science does not differ from genetics in this ethically relevant manner. Quite the contrary, epigenomics should be regarded as partaking to the broader reconfiguration of personal responsibility for one's health, which takes advantage of molecular imaginaries and knowledge of our (epi)genetic individuality, at the basis of the 'empowered patient citizenship' I identified in this work. To the objective of fleshing out the contribution of epigenomics to this political project, I now turn for the remaining of this chapter.

Epigenetic responsibility for health: an empowerment approach

The contribution of the empowerment approach I propose to the appraisal of normative claims of epigenetic responsibility can follow two pathways. On the one hand, my understanding of empowerment could be seen as providing further normative ground to the rebuttal of apportions of epigenetic responsibility at the individual level (Hedlund 2012, Chadwick and O'Connor 2013, Rothstein 2013). On the other, it is worth investigating how epigenomic knowledge – with all the provisos thus far enumerated – represents a unique kind of contribution to the *patient citizenship* project of empowerment in EBRs and Personalised Medicine (PM).

As shown in Chapter 4, I argued that responsibility matters could hardly be solved, from the premises of empowerment, through a mere focus on freedom-of-choice as a condition for attributions of moral accountability. Quite the contrary, the empowerment approach frames individual agency as inextricably related to the capacity of the individual to operate transformations at the level of interpersonal relationships, community action and political agency (Wallerstein and Bernstein 1988, Laverack 2005, Tengland 2008, 2012). Attending to the moral judgement of individual responsibility for one's epigenetic aberrant states means therefore, to the view defended in this work, examining whether the individual (and not merely her choices) is in a *state* of freedom-as-mastery of the politically and socially contextual *process* that is expected to produce the empowering outcome.

This suggestion naturally prompts us to rethinking the dichotomy between individual and collective epigenetic responsibility (Chadwick and O'Connor 2013), and to rather look at the potential ways to promote an 'ecological model' (Minkler 1999) of epigenetic responsibility. The normative declension of this notion would point to (i) questions of access to relevant epigenetic information and knowledge; (ii) to the importance of epigenetic literacy as not only an understanding of a set of instructions (Jennings 2003), but also as a capacity to act upon this knowledge in a social context; (iii) to the existence of effective resources and opportunities provided to an individual, or a community to act upon this information; (iv) to the importance of creating an active public with common values, needs and goals with regard to aberrant epigenetic states; (v) to the fundamental role and obligation on the side of professionals to provide epigenetic counselling through empowering means and relationships (see *infra* Chapter 2 and 5). Only if these kinds of measures are taken up, we are likely to obtain the conditions for empowered freedom at the basis of an *ecological* model of apportioning epigenetic responsibility.

But besides this conceptual movement from empowerment to epigenomics, as a suitable framework to address the social concerns mobilized by epigenetic facts, there is another potential synergy between them which rather looks at *what epigenomics can do for empowerment*. I have already reiterated the multiple ways in which epigenomics promises to unveil the molecular effects of lifestyles and environmental exposures in an accessible, unified read-out (or 'biodosimeter'; see Landecker and Panofsky 2013) of one's epigenome (see *infra* Chapter 6). At the same time, I have also expressed (in this chapter) some legitimate concern as to the current limitations in the analytic, clinical validity and clinical utility of this knowledge that, at least for the moment, demand taking this promise as an encouraging but yet unrealized one. Nevertheless, it is worth noting how, should this promise be fulfilled, epigenomics will most likely revolutionize epidemiological data, values, conceptual premises and facts in our understanding of public health. Health and disease, needs and desires, pathological and social conditions, health inequalities and disadvantage all get embedded in a discourse of digital maps of DNA methylation, chromatin modifications and genome expression (Meloni and Testa 2014). We have already witnessed how this potential of epigenomics may soon become reality, in the discussion of the seminal study by McGuinness and colleagues (2012) on the epigenetic roots of health inequalities in Glasgow. Levels of DNA methylation have the potential to make visible (Nowotny and Testa 2011) how biographies and community-membership, social structures and barriers get embodied through the porous molecular conduit that connects our genome to its environment. This is – in essence – the descriptive powerful narrative inaugurated by epigenomics, which becomes also a normative one when regarded as a premise for the development of public policies, as well as individual and collective action for change (Landecker and Panofsky 2013).

In particular, this paradigm-shift in the understanding of the social *and* biological roots of health and disease outlines a promising social program when juxtaposed to the substantive foundations of empowerment I laid in this work. It has already been pointed out how the language of epigenomics may become a useful heuristics for research on and regulation of our social life (Dupras et al. 2012, Landecker and Panofsky 2013). To this recognition I add that it is possible that, under certain conditions, this project may become a genuinely *empowering* one. Sufficiently valid, reliable and actionable epigenetic knowledge may provide comprehensive information on one's health disadvantages and social deprivations. While confirming the direct link among environment, lifestyles and individual health outcomes, epigenomics can illuminate the limitations of one's power to remedy to health problems or mitigate the structural effects that social arrangements have over the patterning of health in our societies (Marmot and Wilkinson 2003, World Health Organization 2013). This is *the* empowering step I envisage in the social unfolding of epigenomics, to which my normative analysis of empowerment could provide ethical guidance. Through the deployment of sufficiently supportive counselling services (see *infra* Chapter 2), epigenetic knowledge may constitute a genuine opportunity for seizing responsibility (see *infra* Chapter 4) with regard to one's vital goals and health (see *infra* Chapter 3). Rather than being understood as a technological device lending itself to the dubious (for both moral and epistemic reasons) political objective of inculcating responsibility for health, epigenomics can become – through the lens of my account of empowerment – a liberating set of knowledge that inspires collective action, proactive patient citizenship (see *infra* Chapter 1), and political change in the environmental and societal conditions that have a *power over* individual health.

A new epigenetic biopolitics is entailed in the developments and applications of epigenomic science to healthcare contexts, which will most likely reframe the embodiment of people's social conditions in a descriptive and revealing molecular language (Meloni and Testa

2014). One possibility of governing its rise, I suggest, is putting this endeavour under the aegis of empowerment where such knowledge may inform categories of policy-making, identity-making and entitlements, as well as providing an operative map of systematic and socially robust health disadvantages in the general population. Plunging into the biographical and biological roots of health may be regarded, if we attend to the normative perspective I proposed, as genuinely serving the value of an empowered patient citizenship in biomedicine.

General conclusions of the thesis

The analytical pathway followed by this thesis is a long and complex trajectory. I started from mapping a "new wave" of empowerment thinking in healthcare policy-making, epitomized by the emergence of numerous empowerment-based reforms (EBRs) (see *infra* Chapter 1). I observed that a reconfiguration of the substantive foundations of the approach has taken place in the last decade thanks to a number of EBRs emphasizing the alleged promise of empowerment to produce an 'anti-paternalistic shift in responsibility for health'. In scrutinizing this "patient revolution" (Richards et al. 2013), I have resorted to the idea that a *patient citizenship* project is underlying EBRs, and that empowerment is *the* key political device to reconfigure the contours of citizenry in the *personalised* future of medicine.

Starting from this recognition, I argued that this paradigm-shift is likely to mobilize some relevant social and ethical concerns, which mainly revolve around the three main evaluative domains (or *sticks*) in the concept (or *bundle*) of empowerment heralding this reconfiguration of agency in healthcare. First, a substantive matter of controversy relates to the promise of this approach to promote an anti-paternalistic model of professional-patient relationship (see *infra* Chapter 2). Building upon some critiques to the effectiveness of empowerment in delivering this promise (Buchanan 2000, Salmon 2004, Juengst et al. 2012), I identified a *paradox* in the ethical appreciation of (some accounts of) empowerment. According to this view, one of the potential outcomes of EBRs is that professionals may mask their paternalistic interferences with the use of the emancipatory and anti-paternalistic ideology of empowerment. In order to overcome this issue I suggested that, if empowerment has to be praised for its non-paternalistic attributes, the element of increased control (and responsibility) over health should be an important element of patient-professional interactions. Changing the power balance by limiting professional control is, for the view I defended, of pivotal importance to attain the goals of empowerment.

Second, I also approached another concern arising from the emphasis of EBRs on the promotion of responsibility for health. This issue, which I called the charge of *healthism*, highlights the possibility that resorting to the language of empowerment may actually constitute a way of imposing to citizens an obligation to conform to social expectations with regard to their health (see *infra* Chapter 3). From the perspective of these critics (Cribb 2005, Holland 2007, Veitch 2010), the main problem with EBRs lies in the ambiguity between enhancing individual opportunities to seize responsibility for determining one's health (e.g. making a decision with regard to a given treatment, or deciding what kinds of services to request), and inculcating a responsibility to protect one's health (e.g. supporting the system's efficiency and sustainability through the adoption of healthier behaviours). The charge of *healthism*, I argued, can be debunked by looking at different understandings of the value of health in the broader framework of empowerment. In particular, I posited that the elements of self-determination and control in the appeals to responsibility isolated in EBRs clash with a deterministic account of health (Boorse 1975, 1997), and rather point to the necessity of embracing a holistic understanding of health (Nordenfelt 1993, 1995, 2001, 2012, *forthcoming*) as a suitable notion of health to attend to the substantive commitments in the empowerment *bundle* of EBRs.

A main issue emerged in conclusion of this analysis. Opening up the value of health to a relativistic and holistic understanding runs the risk of considering *all* choices with regard to the preferred levels of health as *equally* valuable or responsible. This view would ignore the detrimental effects of social arrangements on those who are powerless, and may overlook the importance of addressing unfavourable social conditions to which people may adapt their chosen levels of health (Venkatapuram 2012). In order to counter this issue, I then moved to an analysis of what kind of choices may count as genuinely *responsible* ones in EBRs (see *infra*

Chapter 4). In addressing this issue, I started from a reconstruction of the main arguments (Morreim 1995, Cappelen and Norheim 2005, Feiring 2008, Segall 2009, Voigt 2013) and counter-arguments (Minkler 1999, Wilkinson 1999, Buyx and Prainsack 2012, Brown 2013) for normative claims of responsibility for one's health. Then I discussed how an empowerment perspective on these matters points to an ecological model of attribution of responsibility (Minkler 1999), which emphasizes both the political *opportunities* in which health-related choices are made, and the social influences that shape individual lifestyle and behaviours.

Combining the analysis of these three substantive domains of empowerment in EBRs, I then moved to a potential application of the normative insights gathered in Part 1 of the thesis (see *infra* Chapter 5). In problematizing different methods for the evaluation of empowerment interventions in health promotion (Wallerstein 2006, Herbert et al. 2009, Hudon et al. 2010), I distilled some suggestions for the development of measurements grounded on the perspective I proposed in this work. Differently from what is currently held in the literature on metrics of empowerment, I suggested that the *Pathways* of research – focussing either on instruments for psychological empowerment, or health-related outcomes of empowerment, or community-based empowerment – should rather aim at integrating all of these dimensions in the assessment of its outcomes. This, I concluded, may actually capture the multi-level dimension of the notion of empowerment in EBRs, which spans across individual enablement through professional support, health-related decision-making, and community-based outcomes alike.

In Part 2 of the thesis I then put to test this normative theorization of empowerment in the societal appraisal of epigenomics. I started from a comprehensive map of the contribution of epigenomics to Personalised Medicine (PM), and consequently of the political project inaugurated by EBRs (see *infra* Chapter 6). In particular, I identified the *promises* of epigenomics in the advancement of the personalization of care with regard to three important areas of healthcare: cardio-vascular diseases, neuropsychiatric disorders, and cancer. From lifestyle behaviours and environmental pollutants, to stress reactions and cognitive functions, the main potential of epigenomics is the construction of a unified digital heuristics (Meloni and Testa 2014) for mapping the unfolding of the genome to external stimuli. In doing so, the upshot of epigenomics' influence on PM is the unification of both biological and biographical roots of health and disease. The flip side of this monumental shift in the understanding of the *plasticity* of both disease aetiology and health outcomes, I argued, is the creation of an imaginary of individual and collective *responsibilities* to protect one's epigenome and consequently one's health (Hedlund 2012, Chadwick and O'Connor 2013).

Starting from this recognition, I finally problematized in this chapter the emerging notion of 'epigenetic responsibility'. First, I played out some normative arguments we encountered in Chapter 4 – grounded on considerations of freedom and solidarity – to evaluate claims of individual epigenetic responsibility (Buyx and Prainsack 2012, Brown 2013). Second, I questioned the recognition that, through epigenomics, claims of responsibility acquire a new strength provided by the molecular knowledge of one's contribution to disease development (Hedlund 2012, Chadwick and O'Connor 2013). In countering this view, I argued that we should be careful as to the current explanatory power of epigenome maps in illuminating lifestyle's contribution to disease development. And that this recognition challenges the view that epigenomics promotes a new discourse of responsibility in healthcare. Still many challenges are waiting ahead for the translation of epigenomics into healthcare practice, which question the analytic validity, clinical validity, and clinical utility of this knowledge. State-of-the-art epigenomic medicine is far from providing sufficiently reliable and usable knowledge to direct individuals in acquiring responsibility for the numerous epigenetically mediated influences of their health. Third, I also challenged the notion of epigenetic responsibility as an allegedly specific societal implication of epigenomics rather than genomics. With regard to this, I showed that it is also dubious that epigenomics may represent *the* link between responsibility matters and contemporary biomedicine. It is rather the case that the notion of epigenetic responsibility will build upon the already present emphasis on genetic responsibility, and provide further biotechnological resources to project of the 'empowered patient citizenship' in PM and EBRs.

Finally, I turned to an attempt of understanding epigenetic responsibility from my account of empowerment. As to this matter, I noted how normative claims of accountability to protect one's epigenome could be dismissed on the basis of an empowerment approach to moral responsibility. However, I also identified another possible synergy between the endeavour of epigenomics and the normative framework of empowerment proposed. Provided that epigenome-based analysis can acquire sufficient epistemic value to illuminate the societal *and* biological influences of health (Landecker and Panofsky 2013, Meloni and Testa 2014), I showed how epigenomics may represent indeed an *empowering technology*.

In a remarkable display of potential synergy, I concluded, these two endeavours of contemporary biomedicine may mutually shape their respective normative and epistemic orders alike. And to this purpose, I hope, the analysis presented in this work may provide a desirable ethical guidance.

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Post-script: a forward look on Empowerment-based Reforms

The intersection between empowerment and epigenomics at the basis of this thesis has many implications for the design and implementation of what I called "Empowerment-based Reforms" (EBRs). First of all, it is worth emphasizing how the normative foundations of empowerment defended throughout this work stand in sharp contrast with already existing and popular uses of the concept in the policy-making literature (Colombo et al. 2012). Rather than pointing to the need of opening up the healthcare system's rationale and functioning to consumerist views of healthcare delivery (see *infra* Chapter 1), my account of empowerment points to the radicalism entailed in the approach (Tengland 2008), and to the importance of focusing on the broader societal conditions for fostering empowered health-related agency (see *infra* Chapters 2, 3 and 4). From the role of non-paternalistic professional support, to the relevance of theories of health and ecological thinking about individual responsibility, my normative theorization of empowerment underlines the plethora of social and relational obligations that could ground substantive claims of empowerment in healthcare reform proposals. This recognition raises an important question as to the implications that my account of empowerment may have over the development healthcare policies. On the one hand, it could be argued that the different substantive commitments at the basis of my understanding of empowerment call for abandoning this concept in developing reforms for the healthcare system. To this view, the approach to empowerment I develop in the thesis is more cognate to established scholarship on the role and value of public participation in biomedicine and science citizenship (Prainsack *forthcoming*), than to the policy literature on empowerment. And for this reason, one crucial implication of my thesis would demand acknowledging that ethical foundations of the approach I defend clash with mainstream uses of the concept, to the extent that they require rather refraining from the language of empowerment.

On the other hand, a different reading of my work could stress the continuity that my understanding of empowerment establishes with some specific accounts of the concept in disciplines such as liberatory pedagogy, social psychology, mental health and health promotion (Freire 1972, Rappaport 1987, Wallerstein and Bernstein 1988, Rodwell 1996, Laverack and Labontè 2000). According to this interpretation, it would be rather worth emphasizing that one result of my work is discriminating between more or less ethically problematic interpretations of empowerment (i.e. traditional accounts of empowerment *vis à vis* its 'new wave' in policy-making). Consequently, one its implications may be better allowing the evaluation of policies that resort to this concept, or alternatively provide ethical guidance to the use of empowerment as a basis for reform proposals. Otherwise stated, rather than focusing on the potential conceptual confusions created by competing accounts of empowerment, this reading of my work would rather stress the importance of philosophical analysis for solving the political and ethical controversies attached to current uses of the concept.

Secondly, it is also important to stress not only how the conclusions of my thesis affirm the need of normative thinking for the achievement of empowering social programs (see *infra* Chapters 2, 3 and 4), but also how relevant could the role of (certain types) of knowledge be for the constitution of empowered citizenry. By scrutinizing the impact of epigenetic knowledge on the development and implementation of Personalised Medicine (PM), Part 2 of the thesis highlights in fact the importance that this information may play in instating, developing and delivering an empowerment program in healthcare. Epigenetics may thus be regarded, under certain conditions (see *infra* Chapter 7), as a type of information that could fundamentally contribute to the attainment of the empowerment aims discussed in this work. Better to say, it is precisely through the language of epigenomics that empowering processes in healthcare may take place. As argued in Chapter 7 of the thesis, drawing from examples in the scientific literature (McGuinness et al. 2012), a growing emphasis is currently being put on the role of epigenetic knowledge in tackling social inequalities and healthcare disparities. This means that another implications of this work lies in the opportunity that epigenetic information may become a constitutive aspect of policies addressing the societal conditions that have an impact upon individual health, thus mobilizing the political and social responsibilities for health attached to empowerment processes. Without further indulging on the details of this potentially liberating endeavour, epigenetics may represent what Landecker and Panofsky (2013) have called a 'bio-dosimeter' of health inequalities: the translation of social categories such as 'deprivation', 'social determinants of health', or 'health disadvantage' into the digital format of epigenetic modifications, and functional aberrations of genomic regulations (Meloni and Testa 2014).

Thirdly, and building upon the above recognition, one of the major implications of this thesis is to draw attention on the role that juxtaposing these two technologies of innovation – i.e. the political discourse of empowerment and the molecular language of epigenomics – may play in the broader context of contemporary biopolitics and biomedicine (Rose 2007). Undoubtedly, the proliferation of studies in human populations on the epigenetic biomarkers of social conditions and adversities will contribute to the on-going renegotiations of citizenship and patient responsibilities inaugurated by molecular medicine. Contemporary molecular biopolitics has in fact already taken many forms. From the inauguration of a 'biomedical mode of reproduction' brought about by genetic biotechnologies (Thompson 2005), to the explosion of a new regulatory and 'technological zone' for stem cell and tissue engineering technologies in the EU (Faulkner 2009), the style of thought of molecular biologists is nowadays pervasive in regulating political action and agency as to what counts as 'health', 'disease' and 'illness', as well as with regard to the roles and expectations of citizens as political subjects. Within this moving and changing landscape, what my thesis emphasizes is that a synergy may be established between the ways policy-makers and citizens make sense of their powers and responsibilities for health both in terms of empowerment and in the language of epigenetics. The opportunity that my work may open up is to trigger the development of a perspective on patient citizenship, which combines to the contestation of a given interpretation of empowerment an understanding of what counts as social inequalities, morbidities, and lifestyle-related illnesses imbued with the language of molecular epigenetics. This is, in essence, the biological politics that is stamped in the pages of this work.

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