

Risk, Rewards, and Rational Consent in Healthy Volunteering

Abstract This chapter explores the limitations of the ‘rational’ and ‘capable’ perspective to understanding healthy volunteer involvement in clinical drug trials. The chapter considers sociological approaches to studying risk and rationality. It questions the uncritical ways in which rational choice theory within a liberal economic context has influenced conceptions of individuals in bioethics’ principles about human involvement in clinical drug trials. In conclusion, I show the limitations of the common approaches to understanding healthy volunteer involvement in clinical drug trials.

Keywords Rationality · Bodies · Risk · Clinical drug trials · Value consent · Clinical labour

SOCIOLOGY AND RATIONALITY

Rationality as a concept in everyday life has been of interest in sociology from its inception. In the 19th and early 20th centuries, Marx (1961) and Weber (1978) both looked at questions of motivation and rationality. Weber’s approach focused on explanations for actions. Over time, this work has come to be interpreted as a focus on the verbal justifications or accounts given as reasons for their questioned conduct (Campbell 1996). The approach developed from what Campbell calls the uncritical reading of Wright Mills’s definition of motive as ‘anticipated situational consequences of questioned conduct’ (Mills 1940, 970).

This definition resulted in the rise of what came to be known as the ‘vocabulary of motives tradition of inquiry’ within sociology (Campbell 1996, 101), in which Wright Mills’ definition was taken to refer to how motives are presented as explanations in defence of questioned conduct. But as Campbell argues, this view is contrary to both Weber’s and Wright Mills’ original understanding of motive as a concept. For Wright Mills, motives should not be seen as mere expressions of intentions and separate from actions; rather, the verbalisation of motive is itself an act just as much as the actions or behaviours in question are. Therefore, analysis of motive should consider more than just the words used in the assumption but should also include the context in which the account is given, as well as where the act in question takes place.

To that end, it is fair to say rationality as a concept is a highly contested subject in sociology. Rational choice theorists make several assumptions about individuals as actors (Becker 1993); simply put, these can be summarised as follows; firstly, individuals have preferences and these are reflected in their goals in life in general. These goals are beyond the theorists’ moral, value, and validity judgment, rather, these are accepted as they are. Secondly, individuals are seen as averse to pain but having an affinity for pleasure. Therefore, individuals are considered to be motivated by the need to avoid pain, while maximising net benefits. They engage in a balancing of the costs against benefits. Furthermore, individuals are seen to be selfish in their pursuit of their preferences concerned only with their own benefits. Lastly, people are considered to be rational; by ‘rational’, they refer to individuals having a tendency to behave consistently in their pursuit of their goals, by weighing the gains against the costs, and always choosing an option that leads to maximum net benefit or minimum net cost. These very simplified points sum up what rational choice theorist call ‘the logic of rational choice’ (Becker 1993).

The limitations of this way of looking at people have been well-documented, including arguments that such a view does not consider actions that would otherwise be seen as nonrational. To that end, new approaches focusing on subjective rather than objective rationality have emerged (Horlick-Jones 2005). Despite these limitations, the rational choice theory is still very influential today. It is common in public health and bioethics, as we will discuss later, in the context of neoliberal economics to think of individuals as capable and rational in representing their interests. By neoliberal, I refer to aspects of the liberal traditions that stand against government intervention, in the form

of regulation, in economic matters. In this way, individuals are seen as rational and capable of participating freely in self-regulating markets. State regulation is reduced to creating a milieu that fosters a free market or imposing protectionist policies to favour local industry and commerce. Neoliberal approaches are demonstrated in state policies of privatisation of public services, including aspects of research and deregulation (Massey 2013). As Fisher (2009) observes, neoliberalism also entails the state's transfer of its responsibilities to the individual citizen. All this is packaged and presented in the rhetoric of individual liberties, in which the state should not interfere with individual choices; rather, people should be allowed to participate on their own accord in the market, thereby providing for themselves. Overall, ideas of individuals as rational actors have become useful justifications for policy approaches in market economies.

It is not surprising therefore, that rationality and motivation have been subjects of interest in much sociological debates, precisely focusing on explanations for individual's action, in relation to issues ranging from motivations to the kinds of reasoning used by lay people when engaging with science and medicine. Lay reasoning has been well-documented in recent research, such as a study on health-seeking behaviours in smoking-cessation programmes (Bond et al. 2012) and immunisation. In such sociological studies, the focus has been on finding logic in lay reasoning. For example, Rogers and Pilgrim's (1995) study of public resistance to mass childhood immunisation considered how the public construct their own risk assessments. A study by Hobson-West (2003) explored the logic of public resistance against vaccinations in the UK and the implications of this resistance for public health. Hobson-West argues that rather than seeing public resistance to vaccinations as a misconception of risks, or that public decisions on risk are based on comparisons of individual risk, such conceptions of risk and resistance should instead be seen simply as a different way of comprehending health and disease as categories. A similar anthropological study by Poltorak et al. (2004) considers the contexts in which resistance to measles, mumps and rubella (MMR) vaccination takes place. Their research investigated parental choice in seeking to explain resistance to immunisation and draws attention to the wider social and personal issues that shape parents' views on immunisation. Similarly, Mishra and Graham (2012) explored attempts to prevent cervical cancer using vaccination against the human papilloma virus (HPV). The study focused on the representation of young women as autonomous rational actors in a campaign to reduce cervical cancer in

Canada. In sum, it has become important to explore how people make decisions. In this book, I explore people's motivations to become healthy volunteers and how they account for the attendant risks.

SOCIOLOGICAL CONCEPTIONS OF RISK

Closely linked to attempts to understand rationality has been the focus on lay or public understandings of risk. Risk is a highly contested concept within the social sciences. For centuries, society has attempted to define measure, identify, and predict risk. However, as a concept within social science, risk has become more topical in the recent past (Beck 1992). Risk as a concept relates to the probability of events happening and their potential effects in terms of losses or gains, mostly because of some activity or policy (MØldrup and Morgall 2001; Taylor-Gooby and Zinn 2006). There have been several sociological attempts to theorise risk and today debates about what constitutes risk have become symptomatic of what Giddens (2013) and Beck (1992) call 'risk society'. However, others such as Green (2009) have challenged the usefulness of risk as a concept in sociological analysis of health issues. While this debate is important, it is beyond the scope of this book. However, knowledge of the value of risk in this sociological literature informed my analysis and was useful in conceptualising my lay participants' understanding and decision-making about the riskiness of their activities.

In this book, I discuss risk in relation to how it is mediated or defined by institutions, and from a lay individual's perspective. In relation to expert and institutional conceptions of risk, sociologists such as Wynne (1996) have explored and critiqued common institutional conceptions of risk in technical and analytical terms (Wynne 1996). This institutional conception of risk situates risk as purely a technical issue amenable to expert measurement and ranking using statistical models and thus can be mitigated against (Fiorino 1990). This emanates from institutions insuring against risk through insurance companies; in turn, deriving from fears of individuals suing. This leads to highly risk-averse policies and practices in institutions imposed by insurance companies, for whom a 1% chance of an adverse event will mean large numbers of claims taken across their whole portfolio. Within this context, risk decisions are thought to be the domain of experts who mediate and define risk for the public. In my discussion, this is linked to the institutional

approaches to managing risks and uncertainty (Brown and Calnan 2010) associated with adverse drug reactions in the drug-development process. It is also looked at in terms of the roles played by the MHRA's clinical drug trials assessment and licensing team who evaluate the safety of the chemical compounds in IMP formulations to ascertain drug safety and RECs. Broadly, within this framework, the experts' role is to define, assess, and certify risks as tolerable, and mitigate against risk, while lay individuals are seen as rational and capable of making informed decision if provided with expert information. Hillman (1993) alone and with others, has explored how institutional conceptions of risks of cycling on inner-city roads influences public perceptions of the risks associated with cycling. They argue that the mistaken view that cycling is riskier than travel by car has led to fewer people taking to cycling due to the perceived risk of accidents associated with cycling. This is of significance as it illustrates how institutions and experts play a role in shaping lay views and responses to risk. Horlick-Jones (2004) looked at the emergence of new forms of expertise on risk and how experts are challenged by the changing characteristics of risks itself. Wynne (1996) and Taylor-Gooby and Zinn (2006) among others in their work have explored differences between institutional and lay conceptions of risk. This difference in views means that lay responses to risks are often at odds with expert advice and prescriptions. Walls et al. (2004) explored how presence or lack of what he calls 'critical trust' in the relationship between the lay public and institutions that define and mediate risk influences public responses and actions to risk. Brown and Calnan (2010) have looked at the role of trust between lay individuals and institutions in understanding lay responses to risk. This is discussed to some detail later in this chapter. In short, expert definitions and communications of risk tend to negate people's lived experiences and how these shape people's understanding and engagement with risk.

There has been extensive research on risk and lay individual action in sociology among others relating to lay understandings of health and risk. For instance, taking a broad approach, Horlick-Jones's (2005) paper on logics of risk examines how discussion of public or individual rationality and irrationality often assumes a canonical conception of reason, which posits individuals as purely rational and calculative in their actions (Scott 2000). However, as Horlick-Jones argues, in practice lay public's everyday engagement with and conception of risk is contingent on the context, and thus adopts a more practical reasoning approach than

a canonical approach. Of particular relevance to my argument, on the significance of context in understanding the interaction between health and risk is Bloor's (1995) study of HIV and AIDS transmission. In his work, Bloor explores gay male prostitutes' conception of risk. The study demonstrates how people's engagement with risk is contingent on the contextual power relationships in social interactions. Tulloch and Lupton (2003), among others, look at individual responses to risk in diverse social situations. Peretti-Watel and Moatti (2006) and Peretti-Watel et al. (2007) have explored conceptions of risky behaviours in health promotion settings. Their findings suggest that labelling people who engage in "risky" behaviours as delinquents brings about pressure to conform to social norms. This may make people deny the risky label or even the fact that their actions are actually risky, resulting in an escalation of the risky behaviour. Of interest in Peretti-watel et al. (2007) findings is how repeated engagement with risk results in individuals conceiving of risk as diminishing and in some cases as absent.

In this book, I approach risk by building on Lyng's (2005) concept of edgework, in which he considers risk-taking as related to the 'consequences of political, economic and scientific progress' and their impact on 'health and wellbeing' (Lyng 2009, 107), resulting in public willingness to engage with risk and the advent of positive views of risk-taking behaviours. According to Lyng, this has stemmed from wide-ranging 'neoliberal' policies and political initiatives, specifically in Western societies, which have shifted responsibility for welfare such as health and employment from the state to the individual. In drawing on Lyng's conception of risk, I am focusing on healthy volunteering in clinical drug trials not as a leisure activity but as a form of voluntary risk-taking in which the 'choice' to engage with risk is defined, as in high-risk sports, by class, race, cultural, socioeconomic, and sociopolitical factors.

So far, the studies discussed in this section all have a common theme: understanding individual rationality. Most emphasise the significance of context in understanding risk. In general, with regard to clinical drug trials, society and professionals recognise that people grapple with issues around risk in clinical drug trials and that these are often thought to be resolved by the application of procedures informed by bioethics.

BIOETHICS AND THE LOGIC OF HUMAN INVOLVEMENT IN CLINICAL DRUG TRIALS

The topic under discussion in this book lies at the intersection between healthy volunteering and institutional contexts. While the sociological research I discussed earlier focuses on the rationality of the lay public in relation to risk, the application of the canonical conceptions of rationality has not been limited to economics and psychology (Horlick-Jones 2005). Rather, the influence of established conceptions of individual action can also be seen in disciplines such as bioethics. Discussions regarding human involvement in medical research usually have been considered as the domain of medical ethics or bioethics (Evans 2000).

Bioethics is distinguished from medical ethics in that it is broadly concerned with attending to a variety of new developments in biological sciences. These include ethical concerns emanating from experiments and human involvement in clinical drug trials. Medical ethics, on the other hand, is an older discipline dealing with ethical concerns arising from the practice of medicine (Bosk 1999; Hedgcock 2004). My discussion focuses on bioethics and specifically on the principlist approach (Evans 2000) that guides the practice of medical and pharmaceutical research. Following the ban of forced use of human subjects in medical research at Nuremberg (Scocozza 1989), the guidelines were established with emphasis on voluntary involvement in clinical drug trials. My aim here is not to give a historical account of the Nuremberg code, or to imply that this was the only important event in the history of ethics and medical experimentation. There have been many incidents over the years pertaining to clinical drug trials, illustrated by the Tuskegee (Harris et al. 1996) and thalidomide (Hazelgrove 2002) disasters (outlined in Chap. 1). I raise the Nuremberg code because it made incidents in medical research visible, and it is also a useful reference point for starting to change guidelines and attitudes about human involvement.

Since its inception, the Nuremberg Code has undergone several revisions and has evolved into fundamental guiding principles for human involvement in clinical drug trials internationally. The involvement of WHO in promoting these principles and the signing by many countries of these international codes of practice of medical research are indications of how bioethics has become part of clinical trial organisation and regulation, and is now woven into codes of practice at national

and institutional levels in many countries, including the UK (what I call ‘institutionalised ethics’). Bioethics has become institutionalised in the regulatory system as a tool regulating and legitimising clinical drug trials and is the hub on which the moral practice of pharmaceutical research is based. These principles have been influential in shaping policy debates about human involvement in medical research (Evans 2000; Dingwall 2008). Today debates about safety, consent, and payment of volunteers are imbued with this traditional bioethical discourse, including a commitment to avoid harming participants and, in a larger sense, achieving good. This discussion focuses on the dominant principles-based approach of bioethics, and how they have become socially and institutionally established as a moral platform and linked to ideas of formal rationality (Evans 2000). Here differences should be noted between bioethics as practice and bioethics as a discipline. As a discipline, bioethics is concerned with other principles, such as avoiding harm and duty of care, in addition to autonomy and rational consent. These other principles are equally relevant because they relate to questions about the boundaries between care and medical research in patient involvement in clinical drug trials (Will 2011), which may easily become blurred as medical professionals assume the roles of both researcher and healthcare professional. Here, I consider two principles of bioethics: rational consent or autonomy and voluntarism.

RATIONAL CONSENT AND AUTONOMY

One of the major tenets of biomedical ethics is rational consent. This principle assumes that to ensure and protect participants’ interests in medical or any other research, they should be offered full information (Scocoza 1989; Hoeyer 2009) upon which to base their decision to take part. Within this framework, the provision of full information is considered to resolve most ethical issues as information provision is seen as an enabler for participants to make free and rational decisions about their involvement. Thus, rational consent is seen as counter to tyrannical and paternalistic medical research practices (Weindling 2001; Dingwall 2008). This model of the autonomous individual is consistent with Giddens’s (1991) conceptualisation of a rational, free-acting, and calculative individual, and is attractive to governmental regulatory cultures, particularly in Western neoliberal society with its focus on the autonomous individual and his or her rights.

Autonomy is taken to mean the ability to act freely without restriction or coercion (Beauchamp and Childress 2001). With regard to clinical drug trials, it is often assumed that people take part out of a rational, informed choice. However, using autonomy in such a way negates the social circumstances and the wider social and political contexts in which informed decisions are made. This is because the process of consent takes place within contexts of power and against a backdrop of cultural norms that shape the way freedom and choice are experienced by individuals. In addition, the interactions in which ‘consent’ is given ‘involves continual negotiation of power that is contingent upon the context’ (Lupton 2000, 104) in which the interaction takes place. But one may also draw from Milgram’s (1963) experiments on how those in authority may influence people’s reactions to risk or obedience to requests, thus compromising the consent process. This further illustrates how power imbalances in relationships may affect what people take on trust. Thus people are likely to be less critical and more ready to believe doctors or other medical personnel, who may be seen as rational and altruistic and often are held in high esteem.

VOLUNTARISM

Another key principle of bioethics, and closely linked to the principle of rational consent, is the view that anyone involved in clinical drug trials or medical research should voluntarily take part. As a principle in bioethics, voluntarism dictates that human subjects are expected to consent willingly, coming forward on their own accord and not forced or deceived into taking part. The aim of introducing voluntarism in the Nuremberg code was to restore agency and protect human dignity in medical research. I must emphasise that ‘coercion’ here refers to making people participate in clinical drug trials as research subjects using force or deception, by taking advantage of people’s vulnerable circumstances such as prisoners and slaves. However, coercion was also drawn from economic conceptions of individuals as capable of freely acting and rational action (Becker 1963). To volunteer, therefore, meant people could choose to take part in clinical drug trials without any force, coercion, or deceit. In 1964, the Helsinki Declaration revised the Nuremberg Code to draw specific attention to vulnerable people such as patients, children, and those considered mentally incapable of making their own decisions; these groups would require special protection in law. People who did not fit

these criteria were (and are still) assumed capable of making rational decisions and representing their own interests.

Consequently, this shift to voluntarism destabilised what were then established sources of human subjects for research: vulnerable and captive populations such as prisoners and service personnel. However, it is argued that forceful and deceitful use of prisoners for research in the UK has never been a problem historically. Whether this is true is a matter open to debate. Nonetheless, these groups were now no longer readily available for use in medical research. Subsequently, researchers had to start thinking of new ways of recruiting participants while adhering to the new legislation and requirements regarding recruitment of volunteer human subjects. However, it appears that regulators focused too much on a definition of coercion that involved forcefully and deceitfully recruiting people for medical research. They did not consider the subtler ways in which coercion might work (O'Neill 2003; Moser et al. 2004), particularly the introduction of payments. In other words, paying volunteers was not considered to be seen as a kind of coercion for people who needed money.

A SOCIOLOGICAL CRITIQUE OF THE TWO PRINCIPLES OF BIOETHICS

Payments and Voluntarism

As the business of clinical drug trials grew from the 1970s onwards, human research subjects became a scarce resource. It was during this period that incentives to volunteers were introduced as part of the commercialisation and privatisation of medical research. For instance, by April 1984, there was such a strong commercial interest in setting up clinical trial units that the UK government commissioned a working party to consider issues such as the licensing of clinical trial units, volunteer health and safety, and the impact of payments to volunteers for medical research. The measure came in response to requests by the Medicines Commission, which had become concerned about the increase in clinical drug trials requiring healthy volunteers both in the private sector and in the NHS (Royal College of Physicians 1986). The growth in commercial clinical trial units resulted in a market-oriented approach; healthy volunteers became commodities who could be 'bought' on the

market. Human subjects in medical research came to be viewed as volunteers and capable of rational consent, meaning that from the 1970s onwards, healthy volunteers in particular started to be seen as capable of pursuing and protecting their interests, just as though they were making transactions in a market economy. While it must be acknowledged that in deciding whether to take part in clinical drug trials, subjects are involved in weighing risks against gains, most social scientists (Corrigan 2003; Fisher 2007) argue that if potential participants are promised large sums as rewards for their involvement, it problematises the entire notion of both rational consent and volunteering itself.

This is because payments are at odds with the principle of noncoercive involvement as they raise the possibility that participants being exploited as volunteers are likely to be from economically disadvantaged backgrounds (Schonfeld et al. 2007). This has been found to be true in a variety of studies (Fisher 2015; Petryna 2009; Abadie 2010). All these studies highlight how structural inequalities—among volunteers and professionals and citizens of different countries—and payments to research participants in developing countries undermine the idea of autonomy in consent and raise ethical dilemmas of potential coercion (Fisher 2015; Geissler 2011).

Currently, paying volunteers for involvement in phase 1 clinical drug trials is common practice, though incentives are also common in later-phase studies as well. This illustrates the complexity of payments to volunteers in clinical drug trials. Geissler (2011) looks at how volunteers in an HIV and AIDS vaccine clinical trial in Kenya were offered a bar of soap as an incentive and had their transport costs reimbursed. However, most of the volunteers are thought to have walked to the clinics and the transport refund came to more than the daily cost of living, thus being a kind of payment for participation in the trials. The researchers were aware of the anomaly, yet the official line was that participants were not being paid.

Corrigan's work examines whether participants in clinical drug trials in the UK understand the rational consent process. Petryna focuses on how late-phase clinical drug trials are being increasingly offshored to developing countries in South America, Eastern Europe, Asia, and Africa, in search of populations thought to be less medicated than those in the West (and therefore more likely to volunteer because of their need for medication), economically straitened, and living in countries where costs of clinical drug trials are low and regulation is not as strict as in the West.

Researchers and governments in these countries see pharmaceutical studies as sources of research funding and employment. However, most participants in these trials are poor people who cannot afford healthcare. Anthropological studies by Petryna (2009), Glickman et al. (2009), and Rajan (2006), among others, on the global political economy of pharmaceutical research highlight how the increasing commercialisation and outsourcing of clinical drug trials abroad raise the risk that research will rely unduly—and unjustly—on economically vulnerable populations. These studies challenge Beck’s argument that risks in the ‘risk society’ have been democratised. Schonfeld et al. (2007) argue that the risks in clinical drug trials are borne disproportionately by vulnerable social groups who volunteer for the reward on offer.

This makes the issue of monetary inducement ethically relevant in clinical drug trials. It draws attention to the subtleties of coercion. The difficulty with over-emphasising rationality is that it negates how people with low incomes and those in debt (Weinstein 2001) and/or unemployed see the sums offered for participation in clinical drug trials as life-changing. Of course, for others such sums may offer relatively little inducement. Nor does it account for the ways in which interactions between professionals and the public are based on interdependencies and reciprocities. For instance, studies in the US have found that to gain admission to as many paid clinical drug trials as possible, healthy volunteers were likely to use deception such as denying being on any treatment, using recreational drugs, or involvement in other trials (Bentley and Thacker 2004; Devine et al. 2013). Such practices undermine clinical drug trials as a system of drug development. In addition, this demonstrates how incentives in clinical drug trials are methodologically unsound and inefficient, and undermine the principles of bioethics.

Another observation of note is that at both national and international levels, regulation has been vague if not silent about how payments should be calculated (Lemmens and Elliott 1999). Similarly, there are no clear definitions of how long a healthy volunteer can stay between clinical trial involvements. This silence is symptomatic of the assumption of capability on the part of healthy volunteers to represent their own interests and make rational decisions and government attempts to avoid ‘interfering’ with the market.

Healthy Volunteering: An Economic Exchange and a Form of Labour

In view of the preceding discussion, within medical research today, human involvement may be conceptualised as an economic exchange: healthy individuals are used to test new drugs in exchange for the money offered by research companies (Elliott 2014; Abadie 2010). This exchange can be traced back to mediaeval times. As illustrated in Chap. 1, until recently the captive populations were used as subjects for such trials because it enabled them to receive healthcare and in some cases test the remedies of their masters (Washington 2006; Weinstein 2001). I am aware of arguments that considering human involvement in clinical trial as an economic exchange undermines the ideal of voluntarism and its significance in social relations (Geisler 2011). However, important as the term ‘volunteer’ might be, it would be naïve to ignore how it is used discursively in clinical drug trials to obscure inequalities and the creation of value in clinical drug trials. In Marxist political economic terms, volunteers can be thought of as a type of worker who contributes to the creation of commodities—namely—medicines, which have a market value. ‘Exploitation’ occurs if they are paid less than the portion of value that they create. Anthropologists Petryna (2005, 2009) and Rajan (2006), and sociologists Cooper and Waldby (2002) illustrate how recent biotechnological developments have transformed the bodies of human research subjects and all their constituent parts into valuable material. Blood serves as the basis for immortalised cell lines and is an important commodity in pharmaceutical research. Sperm, embryos, and other body parts such as kidneys have acquired commercial value both to pharmaceutical companies and to the public, especially financially disadvantaged people.

The demand for healthy volunteers in medical research has led pharmaceutical companies to search locally and globally for cheap and accessible subjects. Petryna draws attention to how the application of ethics seems to vary across international boundaries, specifically among populations of different economic status; such variability obscures who governs the conduct of clinical drug trials and who is responsible for protecting the rights of clinical trial participants. Petryna’s notion of ethical variability is significant in this discussion as it points to the need for an interrogation of regulatory frameworks and the interpretation of ethical guidelines. Moreover, professionals with easy access to bodies realise they possess a capital resource (Petryna 2009), despite the risk of harm that

their products and trials hold for humans. The difficulties of recruitment and efficient running of trials have provided a growing market for CROs, which recruit subjects and carry out research on behalf of big pharmaceutical companies, and there is increasing competition for research subjects.

Keeping with the same theme Cooper and Waldby (2002) observe that in post-Fordist political economies, there has been a shift from mass production to service economies and knowledge production. Cooper and Waldby argue that the response of post-industrial economies to emerging economies has been to focus not on mass production but on biotechnological and ontological innovations that would surpass the achievements of the post-industrialisation era. The accompanying policy discourse has focused on the unrealised potentials of biofuels, genome projects, and efforts to harness them for the growth of their economies, with little focus on how ideas move from the lab to products via experiments and clinical drug trials on human subjects. Consequently, the organisation of labour has resulted in flexible work being introduced, the weakening of organised forms of labour replaced by individual contracts in which individuals rather than employers are responsible for the risks and safety at work.

Turning this analytical framework to human involvement in medical research, Cooper and Waldby (2002) illustrate what they call 'clinical labour' in which human bodies are exploited to create value. Here the bodies of some groups have become not only resources, but also a site for clinical research. Of significance is how the body is used in the fertility industry in relation to surrogacy in developing economies such as India, and of course healthy volunteers in clinical drug trials. In this context, therefore, human subjects are seen as individual contractors who are capable of rational action. Since the 1950s, medical technological innovations have increased transfers of body parts in complex operations to save lives or pursue goals such as parenthood. While most of these parts can be harvested from cadavers, organs and tissues such as kidneys and bone marrow from living persons today are common candidates for transfer. It is not only institutions that see the body as a resource; individuals, too, see the potential of their bodies to generate income. Medical actors on both sides of the equation are trying to make the most of this resource. There has recently been a growing supply of surrogate mothers and egg and sperm donations among poor communities in parts of India (Roberts and Scheper-Hughes 2011). Today the pharmaceutical

industry demands increasing numbers of research participants and the search for volunteers has gone beyond national boundaries.

Healthy Volunteering as 'Passive Labour'

The growth in CROs and the global scramble for healthy subjects for clinical drug trials is an illustration of the value that human subjects in research contribute to the bio-economy. I add here that these new forms of value creation challenge common conceptions of 'normal work' and definitions of acceptable means of 'making a living'. In my view, it is through the process of 'passive labour' that value is produced beyond the limits of socially acceptable definitions of 'work'. By passive labour I refer to ways in which different participants in such activities may conceive of their roles such as healthy volunteering as 'non-work'. This is because these activities may not fit with normative definitions of work, as the roles do not involve physically and actively doing something to produce value; yet they produce value for the industry. This relates to how work takes place and is organised in spaces commonly ignored as sites of work in post-Fordist economies as outlined by Cooper and Waldby, coupled with the increasing casualization of work, in what is now referred to as the "gig" economy'. The gig economy is a growing labour market in which people are employed in short and zero hour contracts, paid minimum wage or less, and have no formal employee protections associated with workers' rights. People in these situations are often categorised as self-employed and are thus responsible for their own safety and welfare, while absolving their 'employers' of any contractual responsibility except for paying the agreed fee (Booth 2017; Wilson 2017). This has left many people in vulnerable and exploitative situations. In many ways, healthy volunteers fit in this category, except that their work does not involve physical labour but merely being present in body. Another difference would be that they are paid relatively more compared to those employed on such contracts in other industries such as courier and delivery firms. However, they are all involved in these varied forms of labour at their own risk.

Specifically, for healthy volunteers, it is how inactivity is seen as pointless and yet is crucial to the creation of value for corporate pharmaceutical industries that is of interest in this discussion. This view of inactivity and the body relates to Marx's views on fetishism (Marx 1961); specifically, how the production of value often overlooks the social relations in which value is produced but focuses on the 'objects' being exchanged for

money—in this case, to use Leder’s (1990) term, bodies become absent or invisible. The bodies of participants become mere tools for value production and often talked of as invisible parts of the process. In addition, whereas in Fordism, labour is mainly dependent on manual contributions of labourers, healthy volunteering becomes passive labour as participants do not have to do any manual work. Instead, their bodies become sites on which work is done and thus value is created. Similarly, as Marx views value to be created by those lacking means of production, healthy volunteers are equally those in financially straitened situations lacking the means of production and subsistence. Therefore, in passive labour, work is no longer reliant on the manual contribution of those involved in value creation; rather, it is based on the body itself. In this case, labour is provided by subjecting the body to experiments in clinical drug trials, which create profit-generating medicines for pharmaceutical companies, rather than by manual work. However, similarly as in manual labour, those involved in passive labour are those lacking the means of subsistence. In addition, healthy volunteering can be seen as unskilled flexible labour and in this case participants are seen as independent contractors (Elliot 2014), and involvement is to some extent at their own risk.

More concerning today, healthy volunteering has become routine among some groups, particularly those in financially straitened situations. The work of Abadie, Fisher, and, Tishler and Bartholomae among others in the US shows how some healthy volunteers have come to see their bodies and body parts as resources with which to make a living. It is here that questions about what constitutes an acceptable way of making a living and individual agency collide. Given the commercial prospects of the human body in clinical drug trials, there has been an increase in debates around the role of the human subjects or their bodies. Of interest, here is the fact that in market exchanges, goods swap hands and ownership, whereas in clinical drug trials, healthy volunteers retain the ownership, control, and responsibility of the body while sharing or lending their bodies for research. In addition, as noted in Hochschild’s (1983) work, emotional labour is also relevant here as healthy volunteers do not just offer their bodies for research, but make various kinds of emotional commitments ranging from reluctant money-seeking to being ‘friendly with staff’. This adds to what I call varieties of ‘passivity’ in different types of ‘labour’. The term passive labour is used here as it can be applied to social phenomenon such as art and fashion modelling, where participation solely depends on the body and rarely involves physical activities.

Views of the body as a commodity possessed by autonomous individuals is of concern to medical sociologists. This is because conceiving human subjects as a valuable 'resource' is symptomatic of consumerist, neoliberal tendencies which focuses primarily on free markets, individual liberties, and reduced state regulation (Scheper-Hughes 2000; Sharp 2000). Neoliberal approaches are prevalent in healthcare in the UK, illustrated by the growth of the CRO industry; the emphasis is on choice and the emerging debate about capitalisation of healthcare in which patients are regarded as consumers. Understanding healthy volunteering requires an awareness of how the conduct and regulation of clinical drug trials is influenced by the neoliberal approach, which extends beyond privatisation to include the commodification of the body. Discussions about healthy volunteers are framed within ideas of liberty and consumption while limiting options for the individual with a discourse of altruism and gift relationship, volunteering, rationality, and efficiency. At an institutional level, healthy volunteers become consumers or even individual contractors, as pointed out earlier. However, such an approach masks the suffering and pain endured by many who subject themselves to these trials and obscures the value of the exchanges. Neoliberalism espouses a view of capable, rational, and free individual. Allowing the body to be used in exchange for payment is justified; healthy volunteers are seen as capable, consenting adults who should be allowed to do whatever they wish. Viewing human subjects as rational actors negates the effect of unequal power and disadvantages in trial processes. There is also the assumption that all players have equal access to resources and influence and thus take part in the market on an equal footing with everyone else (Massey 2013).

Another aspect to healthy volunteer involvement in clinical drug trials is how it relates to Scott's (1977) idea of moral economy of the peasant. Scott draws attention to the peasants' need to produce enough to support their families while meeting the social expectations of their society and the risks attendant with survival. Scott explored the struggles of peasants during years of famine in Burma and Vietnam in the 1930s when they demanded access to land, the right to glean on farmlands, and fair market prices. A parallel can be drawn with the ways in which people are living on the margins in the UK today, obviously within a neoliberal context. Social expectations can influence how people respond to social problems such as unemployment, loss of jobs, or even extreme poverty. Questions about healthy volunteering therefore are taken to be ethical

questions about how institutions use human subjects in medical research, asking whether it is right to encourage people to engage with risk by paying them significant sums. Nevertheless, the morality of healthy volunteers is also often questioned by society: why are they so willing to subject their bodies to such risks for the monetary reward offered? Answering these questions requires looking beyond consent and capability, to consider the wider social context in which such decisions take place.

SUMMARY

This chapter drew attention to how rational choice theories and their conceptions of individuals as rational actors have influenced the principles and practice of bioethics, apparent in the practice of clinical drug trials today. While the intention of bioethics was to restore dignity and agency to individuals, the policy actions have had unintended consequences—blind spots in the interaction among agency, power, and inequality and their capacity to shape each other. Theories of economics, rational choice, and motivation are conceived to be a result of people's expressed wants and goals which influence their behaviour or actions. Bioethics applies the rational choice theory in its classic sense, emphasising individual capacity for voluntary action, and assumes people's capability to make informed decisions. Thus, the assumption that adequate provision of information is sufficient to answer ethical questions arising from healthy volunteering. Information provision is regarded as liberating and enables individuals make 'informed' decisions (Corrigan 2003).

However, ethical considerations in healthy volunteering should go beyond this utilitarian view to consider broader aspects of decision-making. This is because, while individuals may be making choices within this framework, rational choice approaches negate the complex interplay of the individual and the wider social and political structures and how these create a milieu in which certain forms of actions are preferable for certain social groups. Neither model accounts for the ways in which power relationships and wider social factors such as employment, income, and cost of living, debts, and social expectations come together to make certain course of actions, such as taking part in clinical drug trials, attractive. Furthermore, in portraying individuals as calculative and focused on financial benefits, this view does not consider actions motivated by norms or routine such as altruism. To understand people's involvement in clinical drug trials requires an approach that considers individual action broadly, without focusing exclusively on issues of risk and reward.

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