DATA, PRIVACY AND THE INDIVIDUAL

INFORMED CONSENT

KEVIN MACNISH
UNIVERSITY OF TWENTE

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Dr. Kevin Macnish

University of Twente

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INTRODUCTION

Consent has been a central issue in research ethics since the mid-twentieth century. It was the first and longest principle of the Nuremberg Code, which itself is "generally seen as the first authoritative statement of consent requirements in biomedical ethics" (Levine, 2008, p. 170; Manson and O'Neill, 2007, p. 2). The primacy of consent entered US law in 1957 (Katz, 2008, p. 92) and was widely accepted with the first and subsequent versions of the Helsinki Declaration in medical ethics (World Medical Association, 2014). It has subsequently entered research ethics more broadly so that it is now a standard requirement across academia (Economic and Social Research Council, 2019; University of Oxford, 2015). Consent is almost universally required whenever academic or clinical research is carried out on human subjects.

The rise in the creation, collection, storage, processing, and use of data relating to people (personal data), has occasioned concern that consent should also be sought for these ends, as highlighted in the passing of the General Data Protection Regulation by the European Parliament (EU Parliament, 2016). In such cases, it is argued, the people to whom the data relate should give consent for those data to be collected and used. While other papers in this project consider the relationship between data and the people to whom those data relate, this paper focuses on the call for consent as a precondition for the collection and use of personal data. In so doing I draw on recent work in medical ethics surrounding consent and introduce work on the ethics of risk to suggest a way forward.

After a brief overview of different types of consent, the paper focuses on a controversy which has developed between Tom Beauchamp and James Childress on the one hand (Beauchamp, 2009; Beauchamp and Childress, 2009), and Onora O'Neill and Neil Manson (2007) on the other. While the former believe that consent is justified on the grounds of respecting autonomy, the latter hold that it is better grounded on a limitation of harm. This debate has significance for the collection of personal data. As we will see below, if Beauchamp and Childress are correct, then the need to respect personal choice regarding data could extend to all uses of personal data, including those derived from but no longer relatable to persons (e.g., data which have been anonymised). By contrast, O'Neill and Manson's position holds that if there is no realistic chance of harm occurring to the originating individual from the use of anonymised data, then no consent for collection or use is required.

I then introduce the suggestion of Jay Katz (2008) that consent is justified as mutual decision-making between doctor and patient. This suggestion leads into a discussion on the ethics of risk, drawing on work by Sven Ove Hansson and Helene Hermansson (e.g. Hansson, 2013; Hermansson, 2010), which concludes with a call to greater levels of participation in decision-making regarding risk. This returns us to Katz's suggestion

which, while not an effective justification for consent, is a valuable process for arriving at many of the aspects that consent seeks to protect.

TYPES OF CONSENT

While the terms 'consent' and 'informed consent' may be used widely (and for brevity I use them here interchangeably), there are several aspects to consent that need to be understood from the outset. The most fundamental distinction is that between what Faden and Beauchamp term sense$_1$ and sense$_2$ (2008). Sense$_1$ consent is a moral notion of authorization whereby a transaction is freely entered into and permitted by an individual. Sense$_2$ consent is a description of the cultural and policy rules by which consent is collected and deemed 'valid' in particular social settings (2008, p. 166). As the authors point out, this means that it is possible to give sense$_1$ consent (moral authorisation) without giving sense$_2$ consent (meeting social norms) if, for instance, certain procedures and guidelines are not followed even though moral authority has been granted. For example, if I give my full, voluntary autonomous consent to a surgeon who will operate on me, but I fail to sign the necessary paperwork prior to the operation, then I am giving sense$_1$ consent, but not sense$_2$ consent. It is similarly possible to give sense$_2$ consent without giving sense$_1$ consent if the proper procedures have been followed but, given that most policies are not watertight, moral authority has not been provided. For example, when I sign a consent form having read, but deeply misunderstood, the associated information sheet regarding what will happen to me once I have signed on the dotted line. Given the focus on ethics rather than institutional structure in this work, this paper focuses primarily on sense$_1$ consent, but will return to sense$_2$ at the close to see how the two can interact usefully. Suffice it to say at this stage that sense$_1$ consent should form the benchmark for sense$_2$ policies and norms; at the same time, we should recognize that sense$_2$ norms are essential for legislating consent and guiding those seeking consent in institutional settings (Faden and Beauchamp, 2008, pp. 168–69).

Beauchamp and Childress identify requirements for (sense$_1$) consent to be valid. The consent must be given by a competent individual following disclosure to that individual of the relevant facts of the matter. That individual must then understand those facts and act voluntarily in giving their consent to the process going ahead in the light of that comprehension (Beauchamp and Childress, 2009, p. 120). In discussing consent, one usually assumes that express consent is what is being referred to (the clear decision to agree to action X). However, consent may also be tacit (expressed by omission of objection or inaction) or implicit (inferred from actions) (Beauchamp and Childress, 2009, p. 107). Both tacit and implicit consent are harder to justify than express consent, as they rely on subjective interpretation as to whether they have been met. Finally, there is a question regarding the default position: is one to start from a default of a person opting-in to action X, or opting-out from action X? The assumption is usually made that people prefer inaction over action, and so a default position from which a person must opt out

from X means that more people are likely to engage in X. Most defaults used by tech companies like Google and Facebook, for example, are privacy-invasive (i.e., they collect more data than is strictly necessary), and most people do not opt out of the default, even when it is possible.

JUSTIFYING CONSENT

I have claimed that consent is a bedrock of contemporary research ethics, stemming back to the Nuremberg Code. However, wide or historical acceptance are no grounds for a moral position. From where, then, does consent derive its 'moral magic' (Hurd, 1996) to change an act that would otherwise be wrong (e.g., accessing someone's personal data) into one that is right? In this section I examine the alternative justifications offered by Beauchamp and Childress (respect for autonomy) and by O'Neil and Manson (limitation of harm) for consent being able to transform an act from one that would normally be wrong to one that is morally acceptable. Following this discussion, I look at a third approach concerning consent and mutual decision-making offered by Jay Katz. His view does not form part of the debate concerning consent as autonomy-preserving or harm-avoiding, but it does present an alternative value for consent which is worth considering.

Consent as Respecting Autonomy

Beauchamp and Childress—two of the most important authorities in medical ethics, who are also frequently taken as a paradigm for discussions of non-medical research ethics—argue that consent is derived from a fundamental respect for persons which derives from the philosophies of Immanuel Kant and John Stuart Mill (Beauchamp and Childress, 2009, p. 103). They point to Kant's Categorical Imperative, 'that respect from autonomy flows from the recognition that all persons have unconditional worth, each having the capacity to determine his or her own moral destiny. To violate a person's autonomy is to treat that person merely as a means' (2009, p. 103). This justification is echoed by Robert Levine who similarly locates it in the Kantian concern not to treat people as mere means (Levine, 2008, p. 171). To respect someone therefore involves treating that person as an end in themselves. In other words, people should be free to decide how they want to live their life; presumably, then, the argument is that consent is a way of making sure any intervention into a person's life is aligned with that person's objectives and values.

However, O'Neill and Manson dispute that this is a justified reading of Kant. They note that Kant's notion of autonomy was a specific and formal property of principles of action that can serve for all. He did not see it as a characteristic of individuals (Manson and O'Neill, 2007, pp. 16–18). Hence, while the Kantian Categorical Imperative invoked by Beauchamp and Childress does indeed hold that persons should not be treated as mere means, this is not an expression of Kantian autonomy. It is curious that despite this attack on their reading of Kant, Beauchamp and Childress continue to justify their position as one that is rooted in Kantian autonomy. Beauchamp does, however, concede that his position at least owes a greater debt to Mill than to Kant (Beauchamp, 2009, p. 60).

Mill's position on autonomy is that a person has a right to self-determination only while they do not harm others or infringe upon their rights. Given that acts requiring consent

generally do or could harm others, they cannot be enacted as self-determination. However, the person subject to the actual or potential harm has the self-determinative right to allow themselves to be put at risk of harm. Beauchamp and Childress describe this as encompassing, 'at a minimum, self-rule that is free from both controlling interferences by others and from certain limitations such as an inadequate understanding that prevents meaningful choice. The autonomous individual acts freely in accordance with a self-chosen plan' (Beauchamp and Childress, 2009, p. 99).

The position taken by Beauchamp and Childress is therefore that the justification for consent is based on the requirement to respect the autonomy of persons. Although they claim that this can be traced back to Kant and Mill, on reflection it appears as if the greater debt is owed to Mill. Recognising this debt will be relevant in understanding the limitations of their account as to why consent is important, as we shall see below.

Consent as Limiting Harm

In contrast to Beauchamp and Childress, Manson and O'Neill locate the justification for consent in the desire to limit harm. 'Consent matters,' they hold, 'because it can be used to protect research subjects and patients against grave wrongs' (Manson and O'Neill, 2007, p. 17). That is, if we insist on consent prior to a harmful act being performed, the agent at risk of harm will presumably deny consent and so avoid the harm occurring. While Manson and O'Neill locate this concern in the Nuremberg Code (2007, pp. 16–17), it can arguably be traced further back to the Hippocratic principle of abstaining from harm.

In locating the justification for consent in avoiding harm, Manson and O'Neill are critical of attempts to ground it in autonomy. They particularly question why non-Kantian autonomy should be fundamental to ethics, noting that it relates to individuals and individual choice, but cannot account for how to deal with public goods (such as public healthcare) and externalities (e.g., unforeseen consequences of public policies) which cannot be chosen by the individual (Manson and O'Neill, 2007, pp. 18–19). They suggest that this notion of autonomy is either a matter of mere choice (i.e. choice made on mere whim) or of rational choice (choice made on the basis of sound reasoning), which introduces the following dilemma.

If autonomy is justified as mere choice, it is not clear why it should be fundamental to ethics. What if choices made are not rational? To justify this position, an argument is needed which will defend why it is that 'mere, sheer' choice, however irrational and poorly informed, should be so elevated (Manson and O'Neill, 2007, p. 20). If one holds to this position, then standardly forbidden practices in liberal societies such as consensual cannibalism, duelling, and gladiatorial combat should all be permitted.

The alternative is to justify autonomy as *rational* choice. This alternative avoids enshrining poor decisions as ethically foundational but sets a high hurdle for gaining consent. Given the practicalities of gaining consent, 'we would then lack reasons for

thinking that ethics is best operationalised by informed consent procedures. Informed consent requirements protect actual choices, which are often not rational' (Manson and O'Neill, 2007, p. 21).

However, the dilemma given by Manson and O'Neill is not as watertight as presented. Responding to the first horn of the dilemma, Beauchamp and Childress could return to Mill and clarify that the right to self-determination only operates within certain constraints (Beauchamp and Childress, 2009, pp. 103, 105). The egregiousness of the aforementioned acts could fall outside of those constraints, although justifications would be needed to support such exclusion.

In response to the second horn of the dilemma, Beauchamp and Childress argue that 'actions … can be autonomous by degrees. (…) [A] broad continuum exists on which autonomy stretches from being fully present to being wholly absent. (…) For an action to qualify as autonomous in our account, it needs only a substantial degree of understanding and freedom from constraint, not a full understanding or a complete absence of influence. To restrict adequate decision making by patients and research subjects to the ideal of fully or completely autonomous decision making strips their acts of any meaningful place in the practical world, where people's actions are rarely, if ever, fully autonomous' (Beauchamp and Childress, 2009, p. 101).

Manson and O'Neill are therefore attacking a straw man when they challenge the need for autonomy to be based on rational choice, lining up an extreme, idealised version of autonomy which is too demanding for real world scenarios. As Beauchamp and Childress point out, rationality exists on a scale, and all that is required for the Millean justification is that there is a substantial degree of autonomy to ground the justification for informed consent.

In summary, there are at least two competing visions for the justification of consent: that based on autonomy (Beauchamp and Childress) and that on limiting harm (Manson and O'Neill). The former locates itself in a tradition stemming back to Kant and Mill. We have seen that the Kantian defence of autonomy is at best limited, at worst wrong. Autonomy, according to Kant, is not a characteristic of individuals but of actions. However, the Millean defence (freedom to live one's life as one chooses) seems to hold more potential, as recognized by Beauchamp. We have also seen that Manson and O'Neill attack the Millean defence by introducing a dilemma regarding the nature of choice, but that this is answerable by the recognition that Mill allows for reasonable limitations. The Millean defence also accepts that rationality exists on a continuum such that decisions can be more or less rational, rather than the binary position presented by Manson and O'Neill.

While this section defends Beauchamp and Childress's autonomy-based position, it should be recognized that their stance comes at a cost. Manson and O'Neill are concerned that requirements on personal data not being used unless specific, informed, explicit consent is given may be too demanding and prove harmful: 'prohibiting all further uses of legitimately held information would damage patients (by restricting the information that their doctors can bring to bear on their treatment) and the public interest (by limiting medical research)' (Manson and O'Neill, 2007, p. 24). The elevation of personal autonomy can therefore imply, in the case of at least some data collection and use such as medical data, a heavy penalty on individuals and the public interest.

It may be argued that medical data are so special to the public interest that consent arguments centred on such data should not be used as paradigm examples for other data collection, such as that in the corporate sphere. In that case the elevation of autonomy may be seen to occur at the expense of a company making profit, and so many might feel that this is simply a cost the company should bear. However, this view seems overly simplistic. If we put the argument in terms of collecting data for the purposes of cybersecurity, then, as with medical data, the public interest is high. Were it to be demonstrated that a failure to collect large swathes of general, anonymised data could undermine a company's ability to provide robust cybersecurity and thereby secure critical infrastructure, then Manson and O'Neill's point would carry over into the corporate/non-medical sphere. While it is clearly not the case that every instance of data collection is in the general public interest, the fact that the argument can be seen to extend beyond the purely medical realm gives it currency outside that realm.

Mutual Decision-Making

Jay Katz has presented a third alternative to the above justifications of consent. His position is that consent is justified as a procedural act of mutual decision-making between doctor and patient. He argues that this process 'is morally imperative because patients, depending on the lifestyle they wish to lead during and after treatment, must be given a choice' (Katz, 2008, p. 94), although he does not elucidate why this is the case. He does, though, respond to several reasons as to why such shared decision-making between a doctor and patient would not be feasible.

The first reason against shared decision-making is that the expert knowledge of doctors is not transferrable to the patient. However, as Katz points out, doctors are able to translate technical jargon into the vernacular so that the uninitiated can still make an informed decision (Katz, 2008, p. 93). Secondly, it has been suggested that the mere presence of any illness renders the patient unable to give consent. Katz's somewhat tepid response here is that there is insufficient empirical evidence to justify the claim (Katz, 2008, p. 97). The third objection that Katz considers is that the physicians' commitment to altruism should be enough to guarantee the patient's interests are respected. Yet, as Katz responds, 'altruism cannot promise that physicians will know, without inquiry, patients' needs [or values]' (Katz, 2008, p. 94). The first and third objections are relevant to our context as they may also be used in debates regarding the collection and use of

personal data: that the technicalities are too complex for most people to understand, and that the good intentions of the engineers involved should be enough to assuage any concerns (the Cambridge Analytica scandal notwithstanding) (Cadwalladr and Graham-Harrison, 2018).

Katz's position is dismissed by Faden and Beauchamp as treating informed consent and mutual decision-making as virtually synonymous, which they are not. It is possible to give consent to an action without being involved in the decisions regarding that action (2008, p. 167). Owing to its processual nature, Faden and Beauchamp also hold that Katz's position is grounded more in a discussion of sense$_2$ consent (policies and norms) than it is in sense$_1$ consent (moral authority) (2008, p. 169). This is a fair critique, and certainly Katz's position lacks the intellectual underpinnings found in the positions considered above. Nonetheless, I shall demonstrate below in considering challenges to ethical decision-making in cases of risk that it is not without its merits.

THE ETHICS OF RISK

Whichever justification is preferred for requiring consent, there is agreement that consent is important in situations involving risk. By risk, I mean a possibility of harm occurring to someone— typically the research subject. As Beauchamp and Childress point out, 'in general, research cannot be justified if significant risk is involved and subjects are not informed that they are being placed at risk' (2009, p. 126). Risk involves two elements: the chance of harm occurring and the severity of the harm that might occur (Hansson, 1996, p. 170). We therefore say that taking a risk which has a high chance of losing your life is very risky, while a risk with a low chance of a paper cut is not very risky. A low chance of losing your life and a high chance of a paper cut fall between these extremes.

Clearly, risk is not limited to medical research but affects all areas of life, not least the collection and use of data. Since Latanya Sweeney identified Massachusetts Governor William Weld's personal medical records from a dataset of anonymised information in 1996, there has been a general acceptance that privacy is very difficult to maintain in an age of large datasets (Ohm, 2009; Sweeney, 2013). Even if one dataset is anonymised, as was the case in the Sweeney-Weld case, it can be correlated with other datasets to identify hitherto anonymous individuals. There is hence a chance of harm occurring whenever data are collected and used. The degree of probability will be a factor of the conditions under which the data are collected and stored. Likewise, the severity of the harm will depend on the nature of the data: sensitive information, such as health records, could lead to severe harm; less sensitive information is likely to lead to less severe harm (although, as noted above, less sensitive data in combination with other data sets may allow an analyst to infer sensitive data about a person or group of people from data that did not seem sensitive in isolation).

Any attempt at a precise calculus in ethics is fraught with difficulties, and risk is no exception. The potential to arrive at an integer that reflects risk and can then be compared objectively with other integers (risks) is alluring to some and may draw one away from the actual risk to a mere consideration of the numbers. In the face of this temptation, Sven Ove Hansson has published a significant corpus of work on ethics and risk (2016, 2013, 2010, 2009, 2004, 1996). In line with the breakdown of risk into a

function of severity of harm and probability, I will highlight some of Hansson's work in terms of each of these areas. I will then turn to look at Helene Hermanson's work in considering problems of bias and her proffered solution (Hermansson, 2010, 2005; Hermansson and Hansson, 2007).

One challenge in assessing severity of harm lies in its subjective nature. While the loss of my left hand would be unfortunate, I could still practice philosophy. Were I a concert violinist, though, my career would be over. Within medical ethics, a case that is often discussed is that of the Jehovah's Witness who refuses the blood transfusion that others would happily accept. Beauchamp and Childress write that 'persons may have unconventional beliefs, unusual health problems, or unique family histories that require a different informational base than the reasonable person needs' (2009, p. 123). However, they go on, 'exclusive reliance on a subjective standard does not suffice for either law or ethics because patients often do not know what information is relevant for their deliberations, and we cannot reasonably expect a doctor to do an exhaustive background and character analysis of each patient to determine the relevant information' (2009, p. 124). Hence, we return to the $sense_2$ approach to consent as a procedural approach in institutional settings which may not guarantee consent, but it gets as close as reasonably possible in a real world setting.

Also pertinently subjective are perceptions of risk. While you might think of hang-gliding as a fun way to spend an afternoon, I may be petrified at the thought. This is not because we understand the probability or harms differently, but merely because I have a lower threshold for risk than you and so perceive hang-gliding as excessively risky. On the other hand, I may choose to smoke in the belief that there is a very low probability of my getting cancer tomorrow, and who knows what will happen over the next 20 years? Were there the same probability of my contracting cancer tomorrow as in 20 years then I might quit immediately. So time also plays a role in perceptions of risk. There are numerous other factors that influence how we perceive risk (see Ropeik, 2002 for a good list) but these suffice to make the point that how we approach risk is highly subjective.

A third problem is that which Hansson terms the 'tuxedo fallacy' (Hansson, 2009). This fallacy holds that risk calculations tend to be determined as if in an idealised casino, in which there are no factors complicaing the calculation of chance beyond the number of cards in the deck. That is, the measurement of probability for a particular risk may give the illusion of having a greater degree of certainty than may in fact be the case. It may also neglect uncertainties that might have a significant impact on the end result. On a practical level this is necessary to make a manageable calculation, but at the same time it implies that any attempt to derive a calculation of probability in real-life situations must be a simplification. Not least among these complicating factors are the unanticipated consequences of societal change deriving from the risky activity. For example, the non-consensual pooling of medical data to benefit society may lead to groups opting out of the public health system (if people get upset at their data being used without their consent), putting that system at risk if they then contract contagious diseases. Hence what may at first have been regarded as a high probability of helping society (the non-consensual pooling of data) turns out in fact to have a high probability of harming society (people opting out of public health). These problems are hard to predict by their nature but are significant in arriving at a determination regarding risk.

Finally, there is the problem that we do not know and cannot guarantee the consequences of collecting and using data. In order to properly assess the probability and severity of harm, we need to know in advance what the outcome of the analysis based on the data is likely to be; what the secondary uses of the data will be; whether the data will ever be transferred to a third party; whether the data will be correlated with other datasets in the future, leading to possible re-identification[1]; and whether anonymised data could be used to harm groups of people (which is bad in itself).

Hermansson focusses on problems with differences amongst people in decision-making about risk. She notes that, in relation to differing tolerance thresholds for risk, white males in the West tend to have a far higher tolerance of risk than females and members of minority groups (Hermansson, 2010). This is not surprising given that social preconditions in the West favour white males, but it is sobering to remember that significant decisions in western societies tend to be made by the most risk-prone group. For an example in terms of data management, until relatively recently, a man may not have felt that there was too much risk in clients' addresses being made available; yet female clients, who are more likely to be the victims of domestic abuse and stalking than men, may suffer from such a risk in ways that men may not even consider.

Drawing on the work of Hansson and Hermansson, Jonathan Wolff has noted that there are typically three groups involved in risk decisions, which leads to a risk distribution matrix of five possible scenarios consisting of up to three persons (A, B, and C - below) (Wolff, 2010). In these scenarios, risk may be decided by the same person (A) who stands to gain or lose from the decision (1); by a person (A) who stands to gain nothing from the decision, but another person (B) stands to be both the gainer and the loser (2); from a person (A) who stands to gain from the decision, while another person (B) might lose as a result of the decision (3); by a person (A) who stands to lose from the decision, while another person (B) stands to gain (4); or by a person (A) who stands to neither lose nor gain, but in which the gainer (B) and the loser (C) are different people (5).

Scenario	Decision-maker	Beneficiary	Cost-payer
1.	A	A	A
2.	A	B	B
3.	A	A	B
4.	A	B	A
5.	A	B	C

[1] Not to mention what political circumstances will prevail if and when this occurs, thinking of people whose Jewish grandparents added their ethnicity to parish records in the nineteenth century, only to have these poured over by the Nazis in the twentieth.

This risk matrix should again give us pause for thought when we reflect that those offering reassurances as to the safety of collected data are often those who stand to gain from the collection, with little or nothing to lose, while those who stand to lose will gain little or nothing. This is particularly the case in retail transactions in which a company may gain significant financial benefit from customer insight that far outweighs the cost of distributing nugatory coupons for products in their own stores. This puts the retailer firmly into the camp of being risk prone (Scenario 3 in the above table) and hence more likely to take risks with the data of others. An example of the bad consequences that customers can suffer as a result of the risky decisions of retailers is the now infamous scenario described by Charles Duhigg of the teenager whose father discovered she was pregnant on the basis of vouchers sent to her by the store Target (Duhigg, 2012). In this instance, Target collected the data and used it to send vouchers to customers they believed to be pregnant apparently without due consideration as to the impact that such vouchers might have. In the event described, the father of the teenager was quiescent, but he may have been violently disposed towards his daughter on the grounds of this discovery.

There is hence a concern that decisions are made regarding those with much to lose by those with very little to lose. This asymmetry leads to a situation in which morally dubious decisions exacerbate divisions in society, protecting the privileged and harming the vulnerable. One classic example of this is the Ford Pinto, a car that was inadvertently designed in such a way that, if rear-ended at 20mph or faster, the petrol tank would rupture and the vehicle explode. When Ford became aware of the problem, they decided not to recall the vehicle, as remedying the problem would be more expensive than paying compensation to the victims and their families (which were estimated to be 180 dead and 180 seriously burned). One can be confident that, on hearing of the design flaw, no one in Ford would be driving a Pinto, and yet the risk was allowed to persist for those not so enlightened (Mcginn, 2018, pp. 149–60). Ford were both the decision-maker and beneficiary (in terms of sales and reduced pay out for their mistake) but not the cost-payer, which was the general public. Hence the decision regarding not recalling the Pinto falls into Row 3 of the above table, the most risk-prone row.

The means to improve this situation was found by the US courts, which imposed a heavy punitive fine on Ford. From Ford's perspective, as a result of the fine the scenario effectively moved from Scenario 3 to Scenario 1 in the above table. By having a cost imposed on them, Ford became a cost-payer of their decision to leave faulty cars on the road (albeit not changing the fact that others still bore that cost as well, although the publicity from the court cases would have led to people losing trust in Ford and no longer driving or buying the Pinto). Such a cost came in addition to having to pay compensation to victims and their families.

Drawing the Pinto case back to data collection, there is a risk that corporations involved in data collection often stand in the same relationship to the originators of that data as Ford did to Pinto drivers (and passengers). As with the Pinto case, the means to remedy such tendency towards risk-prone behaviour lies in the hands of the courts and legislators to impose costs on those collecting data, and grant compensation to anyone who can be shown to have suffered harm through that collection.

Finally, there is a concern that arises from the way in which questions of risk are framed. An example is provided by Beauchamp and Childress when they report that the numbers of people agreeing to therapies may depend on whether the question was framed in terms of the probability of survival or the probability of death (2009, p. 130). Indeed, the entire framing of the debate around consent may be a specifically Western construct. Levine argues that, 'the Western vision of the person is a minority viewpoint in the world' (2008, p. 172). He references Willy De Craemer, who argues that in Japanese society there is, 'a never-ending process of mutual giving, receiving and repaying (…) [through which] a web of relations develops that binds donors and recipients together in diffuse, deeply personal and overlapping creditor-debtor ways. Generalized benevolence is involved, but so is generalized obligation' (De Craemer, 1983, p. 30). Hence at least one non-Western culture would hold the potential to withdraw from contributing to a societal good by withholding consent as an ethical wrong.

In the face of the subjective nature of risk, Hansson and Harmansson each recommend the procedural solution of participatory Technology Analysis (pTA) (Hansson, 2009, p. 491; Hermansson, 2010, p. 507). This method involves bringing all stakeholders to the table to discuss the potential impacts of new technologies on all aspects of society and share in decision-making about risk. There are problems with this approach, not least how to represent future generations and how to arrive at a decision to avoid both that a minority group have a disproportionate veto and that they be steamrollered by majority decision-making. Furthermore, there are questions as to how to achieve such balance with stakeholders in big data scenarios in which datasets may be extremely large and anonymous. Similarly, problems arise regarding secondary use of data. However, pTA is consistent with Katz's suggestion of joint decision-making as a solution to the problems outlined in this chapter.[2]

To draw Hermansson and Katz together, the suggestion would be to place the value of consent in a Millean notion of autonomy. I have argued that, despite the criticisms of Manson and O'Neill, this view still carries some force. However, the justification for valuing autonomy comes from the recognition of the inherently subjective nature of decision-making regarding risk. By bringing the person affected (and the group, when groups are affected) to the decision-making table, many of the problems arising from subjectivity can be mitigated to some degree by including representatives from across the spectrum of society. This means that no group or individual should go unrepresented, and thus the decision maker will include any groups or individuals that risk losing out as a result of the decision.

This solution is therefore both a procedural sense$_2$ solution and a moral sense$_1$ solution. It posits the value of consent sense$_1$ in terms of recognizing the right to self-determination and the relevance of the individual in determining what is harm in their own case. It also suggests a procedural sense$_2$ solution as to how to best achieve the harm-limiting function that, as Manson and O'Neill point out, is so crucial to consent. I am

[2] I am grateful to an anonymous reviewer for raising a number of problems with pTA that I had initially missed. The same reviewer also raised the noteworthy problem of effectively informing the subject as to the situation in order to achieve genuine stakeholder participation. This is a significant concern, but no less than the broader problem of informing people of risks in order to secure their consent in the first place. As such, the question of how to effectively inform decision-makers, while important, falls outside the scope of this paper.

proposing that we follow a path that falls midway between the arguments of Beauchamp and Childress and Manson and O'Neill, but one that is strengthened by the insights of each while not falling foul of the criticisms of both.

To apply this recommendation to data, efforts should be made to understand the full complement of stakeholders in data collection, storage and use. These stakeholders should then be approached to engage in the decision-making process as to what should happen to or with the data. Realistically this is not likely to involve every single person affected, but representative focus groups could be created to inform the process. This would ensure that decisions which have the potential to harm some parts of society are not made solely by people who have little knowledge or understanding of those areas of society that stand to suffer.

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