How to Design Consent for Health Data Research? An Analysis of Arguments of Solidarity

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Introduction

Medical research has undergone significant changes in the last decades. Biobanking is on the rise. New tools for data processing, among them developments in Machine Learning, are widely available. Health data is being digitized not primarily for research purposes, but first and foremost to facilitate access and improve treatment. Medical research based on large data sets appears to many to hold an immense potential for significant progress in health care.

Informed consent has been set down as a core ethical requirement for medical research in the Declaration of Helsinki and the Nuremberg Code but was traditionally understood to apply to research with direct involvement of patients (Capron, 2018). As research *without* direct involvement of patients—based solely on collected data or biospecimen—becomes more relevant and prevalent, another set of normative requirements, also operating under the name of consent, comes into play: Gefenas et al. have employed the terms of ‘interventional consent’ and ‘informational consent’ to mark this difference. Informational consent, governed in the European Union today mainly under the General Data Protection Regulation (GDPR) sets the legal standards for processing personal data (Gefenas et al., 2021).

Informed consent to medical research is commonly understood to fall under both sets of norms. Considering that for large-scale studies obtaining individual consent from all persons whose data or samples are used is significantly burdensome, models of broader consent have been suggested as appropriate for such contexts where no forms of physical or other direct interventions are part of the study. The standard of study-specific consent is often considered appropriate for interventional studies, while pointing out that not all research studies involving human subjects *are* interventional and highlighting that the risks of purely biospecimen or data-based research are significantly less—or at least different (Chadwick and Berg, 2001; Hansson et al., 2006; Kasperbauer et al., 2018; Mikkelsen et al., 2019).

In the debate about appropriate consent for biobank and health data research, solidarity has been referenced to argue against too strict demands of informed consent. It is either taken as a basis to argue for broad consent (Prainsack and Buyx, 2017) or even to deny the need for consent (Chadwick and Berg, 2001; Harmon and Mcmahon, 2014). But the claim that it gives us reason to weaken demands of consent has also been contested (Neuhaus, 2020).

A recent empirical study on the preferences of cancer patients in Germany regarding the use of their clinical data shows that a vast majority of participants is willing to support research as long as high-security standards are assured and some other requirements are met (Köngeter et al., 2022). Regarding suggested models of consent, both broad consent as well as data use by default with an option to opt-out reached higher levels of acceptance than specific consent (Köngeter et al., 2022). Tiered consent was not considered in the study. The authors point out that cancer patients might be more willing to support research than other patients in Germany, and from an ethical perspective such a specific group preference cannot be the single guideline for governance decisions—but the results certainly support the idea that study-specific consent today does not have to be regarded as the only option to design consent for research.

Aims of the Paper

In this paper, I will introduce three concepts of solidarity that share some core aspects but differ in regard to the normative claims they make: Solidarity will be considered as a concept describing individual motivation, as

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a concept of a social practice of axiological normativity, as well as a concept of morally required mutual support. I will show how each of these concepts can have a different kind of impact and lead to different conclusions if we refer to it in the context of debates about consent models.

The first concept highlights that individuals have other-related interests and wish to support people they stand in solidarity with as a descriptive fact. In the context of a debate on consent, it can primarily inform us about actual or potential interests of those participants consent models are meant to protect and might be useful to argue for consent models that offer flexibility to those consenting.

The second concept assumes that many, but not all practices of solidarity must be considered valuable and thus have normative impact in such a debate. It has been referenced to argue for broad consent—and I intend to show that it is better suited to defend a form of limited-tiered consent: If the aim is to allow participants to give maximum support to research based on their motivations of solidarity, we should allow for differing solidarities to be expressed but limit those forms of solidarity that might further existing injustices.

The third concept of solidarity as a moral duty must be considered as the most powerful in the context of applied ethical debate and appears best suited to argue for broad consent. It might even be considered an appropriate basis to argue for the permissibility of health data research without consent. As it is tied to justice, however, it also raises questions on what exactly has to be regarded as just in the context of medical research.

Models of Consent

Let us assume that a patient who has long been suffering from a rare disease is admitted to a clinic and discovered to have cancer. The clinic is currently running two studies, A and B, where A is a study related to cancer and B is related to the patient's rare disease. In the course of the next 5 years, two more studies will be started, C and D, one again related to cancer and one to the rare disease. All studies are purely data-based and do not require any direct involvement of the patient.

If the clinic were to use specific consent, the patient would now be informed about studies A and B and be asked to consent. Separate procedures of disclosing information and requesting consent for studies C and D would be required in the future.

In the case of broad consent, the patient would be informed about the guidelines of clinical research in general, possibly with some brief information about ongoing studies, including A and B, and would either consent to all studies (including C and D even though they are not yet foreseen) or to none at all.

Tiered consent has been suggested as a flexible compromise between study-specific and broad consent (Bunnik et al., 2013). In our example, the patient could choose to select only specific studies (A and B) or to give broad consent (covering A, B, C and D). In addition, she would have the option to give consent only to all cancer-related studies (A and C) or to those studies related to her rare disease (B and D). For a detailed discussion of these models and their advantages and disadvantages from an ethical point of view see Wiertz and Boldt (2022).

A separate issue discussed in the literature refers to the option of digitizing consent processes so that the individual consent profile of a person can be saved and changed over an online platform (Ploug and Holm, 2015; Budin-Ljøsne et al., 2017). Online access to such a tool is meant to improve accessibility and transparency for patients, while the underlying digital consent management can be considered a necessity for responsibly managing any system of consent that goes beyond agreement to specific studies (Wiertz and Boldt, 2023). Concerns regarding the danger of deepening the already existing *digital divide* and how to best mitigate them have been discussed (Prictor et al., 2018).

Whether the implementation is digital or not does not affect the scope of the consent given. In principle, specific consent as well as tiered or broad consent can be implemented as paper forms or as a digital infrastructure. As questions of solidarity generally relate to the scope of the consent and not the form of its implementation, this aspect of the debate will be ignored here, even though some connections to considerations of accessibility and effort could be drawn.

Concepts of Solidarity

Solidarity has been discussed in a diversity of fields and contexts. While the term originates in Roman law, its understanding today is deeply tied to its use in the context of the French Revolution as well as the international labour movement (Laitinen and Pessi, 2015; Schmale, 2017; Bude, 2019). Today it is prevalent in social theory in discussions of group identity, in political activism as a call for action, and has been employed in a number of different functions in medical contexts, not last to describe European systems of health insurance (Prainsack and Buyx, 2016).

Solidarity is related to human actions of support (as a motivation or as a practice in which individual acts are embedded) based on an assumption of some relevant similarity and as part of some system that involves a degree of indirect reciprocity. While the term is sometimes employed to describe institutionalized and legally regulated practices (like health insurance systems) this seems to be best regarded as a derivative use of the term.[1]

Solidarity can always be understood as normative in so far as actions of solidarity are dictated by social norms and directed at the realization of some good. In ethical debates, however, it is important to differentiate between concepts of solidarity that come with a normative claim (usually the claim that people should perform solidary action) and those without such a claim. In the latter case, the concept is aimed at describing a phenomenon without attaching any judgement on whether it describes good or bad action—on whether one *should* or *should not* act out of solidarity.

Whether or not a concept of solidarity encompasses such a claim is highly relevant for its scope: Many actions or practices that appear as solidary on a descriptive level have been shown to be exclusionary and to the detriment of those not belonging to the relevant group (Kaphegyi et al., 2022). I will refer to this as the dark side of solidarity. The problem is this: Solidarity is a group phenomenon, and thus creates an in-group and out-group dynamic, a differentiation between those who are part of the practice and those who are not. Traditionally, solidarity between white men has been strong to the detriment of women and people of colour. Today, this is a kind of solidarity we do not want to foster. Similarly, we do not deem furthering the solidarity among doctors against the interests of patients valuable. Nor should a liberal democratic society devoted to non-discrimination support solidarity among defenders of heteronormativity against members of LGBTQ+ communities.

Many conceptions of solidarity that have been suggested are not clear on where they stand in regard to the normative claim of the concept. The following discussion focuses on positions that do take a stance in this context and assumes that any concept of solidarity should be explicit in this regard—particularly if it is to be employed in an applied ethical debate.

The first concept I will consider here is one that takes a predominantly descriptive approach and asks what conclusions we can derive from the insight that people do, in fact, act and wish to act out of solidarity.

The second and third concepts both lean towards the normative approach and claim that there is a certain value to be found in practices of solidarity which gives us reason to encourage solidary practices. For the second concept, this claim is weakened by the acceptance that not all practices of solidarity must be considered valuable as some of them might aim at the realization of goods for those participating to the detriment of others who are excluded.

The third approach conceptualizes solidarity as ethically valuable and closely tied to considerations of justice. It is thus much more straightforward in allowing us to draw normative conclusions with the disadvantage of making it harder to determine whether a practice should be considered solidary or not—it needs to be proven to further (or at least not hinder) justice, first.

A Descriptive Concept of Solidarity

The first concept of solidarity can be expressed like this: Persons are sometimes, through recognition of some commonality with others, motivated to act in the interest of another person. Solidary action exists in a group that identifies over some shared attribute (real or imagined) and is perceived as reciprocal. Bonds of solidarity can exist in smaller or larger groups and be oriented to different goals and values. Within the group, solidarity creates rights and obligations for its members (Tranow, 2012; Lahusen, 2020). In this sense, white men giving preference to other white men of comparable social standing in hiring procedures can be understood as an expression of solidarity.

Is such a concept even of interest for an ethical debate if it includes no claim regarding how the world *should* be? Hummel and Braun (2020), while discussing a more demanding concept of solidarity, point out that some conclusions can be drawn based on nothing more than the observation that some actions can appropriately be described as solidary:

> We do not claim that individual attitudes cohere with pictures of solidarity and gift-giving in the sense outlined above uniformly, consistently, and with statistical significance. We propose these pictures not as empirical claims about the motivations and attitudes of a majority of individuals, but as descriptive schemes to capture a set of target phenomena in all its complexity. Our claim is not that we must employ the descriptive schemes of gift-giving and solidarity when framing decisions to share personal health data, just that these schemes highlight attitudes, motivations, and

> intentions that might have otherwise escaped our attention. (Hummel and Braun, 2020: 6)

Even if other options of describing a certain phenomenon are open to us, describing an action as motivated by solidarity allows us to understand the world around us in a certain manner. It allows us to see that at least some people act out of motives that cannot adequately be described as solely self-interested.

Thus, acknowledging descriptive solidarity is of relevance to ethical debates insofar as it informs us about actual or reasonably assumed interests of stakeholders.

Solidarity of Axiological Normativity

Most accounts of solidarity favour a normative approach: People *should* act out of solidarity. The inherent claim is that practices of solidarity are valuable not only to those participating in them, but that they can be judged to be valuable from the outside: from an impartial point of view, a society with solidary practices is to be preferred over one without solidary practices.

In bioethics, one such account has been suggested by Prainsack and Buyx. These two authors defend an account that is predominantly descriptive, but also encompasses a normative dimension. For them, solidarity is best characterized as a group of social practices which realize a 'commitment to carry "costs" (financial, social, emotional or otherwise) to assist others with whom a person or persons recognise similarity in a relevant respect' (Prainsack and Buyx, 2017: 52).

The shift of attention from individual motivation and actions to group practices is interesting but not of great relevance here. It is important to notice that the value of solidarity is seen in the practice as a whole, more than in the individual action. But one could easily argue that in the descriptive account as well, actions and motivations must be understood in the context of social practices.

While solidarity in itself is taken to be valuable, in the account of Prainsack and Buyx this does not lead us to the conclusion that any act taken in the context of a practice of solidarity is overall laudable. The authors acknowledge the dark side of solidarity: the potential of solidarity to further the interests of one group to the disadvantage of others (Kaphegyi et al., 2022).

Prainsack and Buyx suggest to differentiate between a field of deontic normativity and a field of axiological normativity. It is deontic normativity that is concerned with central human values and it is such values, as, for example, justice, that generate moral duties. The normativity of solidarity is not of this kind but should be regarded as secondary. Solidarity can have a supportive function in realizing justice and as such, derives its normative impact from this function. Prainsack and Buyx assume that persons have no moral duty to act in solidarity with others, even though such actions might appear in some circumstances as laudable (Prainsack and Buyx, 2017).

This leaves us with the task of differentiating between overall valuable (actions and) practices and overall harmful (actions and) practices as both can occur as instances of solidarity. Is there an easy way to tell both apart? Prainsack und Buyx seem to suggest so when they cite a 'solidaristic principle that mandates that we act upon what connects us to others and not on what sets us apart' (Prainsack and Buyx, 2017: 102) but they elaborate little on this aside from a vague suggestion:

> In many contexts, this will mean that solidarity practised on the basis of common traits shared by wide groups of people, or even all people, is preferable over solidaristic practice based on more specific—and thus more exclusive—characteristics. (Prainsack and Buyx, 2017: 72)

However, this solution is not convincing. When I stand in solidarity with women, I do so based on the recognition of a relevant similarity—our sex or possibly our position in society as belonging to the female gender. While I do so, I mark a difference to the male sex or gender. In the same way, a man might see himself in solidarity to other men, without the intention of discriminating against women. In short: Picking any given similarity that is not shared by all of humankind constitutes an exclusion of all those who do not share it. Whether that is my primary intention or just a secondary effect might matter, or it might not. In the given example, me standing in solidarity with women seems acceptable in a way that my colleague choosing solidarity with fellow men does not, even though both groups are of comparable size. This is not due to any inherent property of the quality we chose as a basis to identify with others but due to the given socio-historical context—women have been and still are disadvantaged in many ways in our society while men are not. The one practice can be seen as suitable to counter a given structural injustice while the other would likely perpetuate it. It seems no less justifiable for transwomen to act in solidarity with other transwomen even though the relevant group is much smaller.

While this account tries to take a middle ground between a descriptive concept and a normative concept of solidarity, its weakness lies in not offering a clear answer on how to determine where solidarity, generally to be considered as valuable, takes on a harmful form and should no longer be supported.

Solidarity as Tied to Justice

The third type of a concept of solidarity I want to look at here addresses the problem of the dark side of solidarity by assuming that only those social practices count as *normative solidarity* that have to be considered as overall valuable. If they are problematic, they disqualify as falling under the concept, at least in its normative sense. I take Carol Gould's (2018) account of networking solidarity as a prominent example of such an account.

Gould declares the pursuit of some kind of benefit as insufficient to characterize practices of solidarity. Instead, solidarity is aimed at 'overcoming domination and exploitation' in the face of structural injustice (Gould, 2018: 543). While a shared vulnerability is recognized, the sense of 'we' it presupposes is partially created through the shared action towards its cause and the reciprocity of solidarity as well has to be understood as referring to shared action and a shared commitment to justice.

As Kolers points out, the inherent advantage of such a free-standing account is that in itself it allows us to make evaluative assessments of actions instead of having to reference some external value (Kolers, 2020). And considering that Gould aims to strengthen the normative aspect it is no surprise that she talks about 'obligations' of solidarity (Gould, 2018: 542). Following the differentiation between deontic and axiological normativity from above, I understand normative solidarity as falling into the realm of deontic normativity.

It is of interest to note here, that the moral duty (obligation or responsibility) we carry in this case is again derived from justice as in the case of the concept introduced above. Only for normative solidarity, the connection between solidarity and justice is understood as necessary, and thus can be assumed to hold in every case. What exactly that means in regard to actions of solidarity depends on the normative account we refer to. If we follow strict utilitarian arguments we might have a straightforward duty to act in solidarity with others if this improves overall outcomes. If we take objections related to a danger of excessive moral demands seriously, we might prefer to think of each person having a limited responsibility to realize justice (Young, 2006; Gould, 2018). Or, in a Kantian system, we could talk about an imperfect duty of solidarity—we have some obligation to improve the situation of those treated unfairly but a good amount of choice in deciding how to fulfil it (Johnson and Cureton, 2022; Kant, 1968: 421–424). In either case, I do something morally wrong if I refuse to take any action of solidarity at all.

It should be clear that a concept of solidarity as tied to justice carries greater weight in the context of an applied ethical debate than either of the other two. It points at the realization of a core social value and can be referenced to argue for moral duties of solidarity.

Solidarity in the Context of Consent Debates

Descriptive Solidarity

In the context of debates about consent, it has been argued that the standard of study-specific consent needs to be upheld to protect the autonomy of research participants. Any given consent needs to be sufficiently informed to be adequate for protecting their right to self-determination (Caulfield and Kaye, 2009; Caulfield and Murdoch, 2017). This line of argument has been countered by questioning any given definition of 'sufficient' information, reference to actual lack of understanding by many research participants (Beskow and Weinfurt, 2019), as well as lack of interest (Campbell, 2007) and not least the debate of the phenomenon of 'consent fatigue'—the assumption that research participants are less likely to actually absorb information the more often they are confronted with it (Cambon-Thomsen, 2004; Ploug and Holm, 2013). If we wish to take into consideration the interests of research subjects beyond upholding an abstract philosophical ideal of autonomy, descriptive solidarity might be an interesting concept to employ.

A descriptive concept of solidarity informs us about the interests and motivations of a certain group of stakeholders in a given context of applied ethics. In the context of consent, a practice that is *designed* to protect the interests of research participants in the first place, this certainly appears relevant. Descriptive solidarity informs us that a person's interests are not only, and maybe not even most often, self-directed. People act and wish to act out of solidarity and those actions are directed at the well-being of others. Hansson et al. (2006) point out that broad consent can be understood to protect a person's interests better than specific consent in one sense at least: If people are well informed about research in general and wish to support it as widely as possible, we are limiting one valuable path of action for them by not allowing broad consent. This is an argument that does not need to rely on a concept of solidarity. But it is at the same time a perspective we are more likely to appreciate if we keep descriptive solidarity in mind.

What interests do specific models of consent protect? Specific consent can be taken to be most in line with the preferences of individuals who are concerned about the risks they face if their data or specimen are used in a study. It also appears well suited for those who are doubtful about the actual usefulness of many medical studies conducted.

Broad consent appears to best reflect the interests of individuals who wish to support medical research as broadly and efficiently as they can, likely from a solidaristic or altruistic motivation. While in our example they could participate in all studies, A, B, C and D, no matter if they give specific or broad consent, it cannot be overlooked that asking them for specific consent is the less efficient process, increasing the cost for each study, as well as the time investment required on the side of participants.

Tiered consent appears best for those individuals who wish to express their solidarity with a specific group. In our case, anyone who is not generally enthusiastic about supporting medical research but wishes to further either research on rare diseases or cancer specifically can be assumed to prefer the options given by tiered consent. But it can also accommodate the interests of other individuals in so far as it is the model with the highest degree of flexibility: tiered consent can accommodate individual selection of either study-specific or broad consent.

Overall, the implications of descriptive solidarity can be taken as an argument for allowing broader forms of consent. We have at least some reason to take individuals' preferences into account. Considerations of solidarity remind us that such interests can be other directed and that there are many ways in which persons wish to support others—often because they recognize a degree of similarity in a relevant sense and wish to take part in a practice of reciprocal support.

As descriptive solidarity refers to people's actual motivations, a weakness of the argument above is that it refers to assumed (reasonable) interests of persons instead of referring to actual interests of, for example, the citizens of a country. If we want to take the descriptive level seriously, we should conduct more empirical research and gain information on people's actual interests and preferences. The value of options of tiered consent must be regarded differently depending on whether 99 per cent of a population favour broad consent or whether only 50 per cent consider it acceptable at all. Actual practices of solidarity should inform which categories a model of tiered consent should offer.

Solidarity of Axiological Normativity

The axiological account of solidarity keeps many of the elements of the descriptive account: It assumes that there are many practices of solidarity that we can engage in and that individuals do have no moral duty to engage in any of them, but might very well wish to engage in some. Indeed, there are normative reasons to engage in solidary practices even though we have no moral duty to do so. At the same time, some practices of solidarity might be objectionable from a moral point of view as they disadvantage those not participating in the practice.

Practices of solidarity can be based on different perceived similarities. General vulnerability of human beings to disease would be one relevant similarity in the context of health research, but many others might come to mind. Solidarity among groups that perceive themselves as having been overlooked in the past—be it women, trans persons, or carriers of rare diseases—as well as family or ethnicity-oriented solidarity in the context of genetically transmitted conditions appear plausible.

Prainsack and Buyx neglect this aspect of their own account when they argue in favour of broad consent. They point out that people wish to support public research biobanks out of solidarity and argue that they should be allowed to do so as long as appropriate governance structures are in place. But they do not further consider their potential wish to express *different* solidarities (Prainsack and Buyx, 2013). If we assume that there are no objectionable practices to be found in the realm of consent for research, we should allow people to establish as many solidary practices as possible. So, we should give people the option to act in solidarity with all other humans, or all women, all cancer patients, etc. For this purpose, tiered consent must once again appear best.

Broad consent allows for the expression of solidarity in one sense and one sense alone—it can be understood as a practice of solidarity encompassing all of those who contribute to and profit from this research. But if we consider solidarity among particular groups—cancer patients, or carriers of rare disease, an expression of this practice of solidarity is not possible when we introduce a model of broad consent. If we wished to support as many practices of solidarity as possible, we would have to introduce corresponding options for consent—in our example, consent to research regarding cancer (studies

A and C) or rare diseases (B and D). This is what a model of tiered consent is designed to allow.

Considering the dark side of solidarity, we have to acknowledge that even in the context of health research there might be categories that trace objectionable practices of solidarity. In particular, consent categories that exclude already disadvantaged groups from the benefits of medical research cannot be defended by referring to their status as practices of solidarity. They must be seen as ethically objectionable. If, for example, we consider offering people the option to specifically exclude use of their data and biospecimens for AIDS research, while knowing about existing prejudices about persons who are HIV positive, we have to realize that we are facilitating existing injustices. White people should not be offered the option to exclude the use of their data and biomaterial from the use for any studies that are concerned specifically with the health of People of Colour, even if they do so out of solidarity amongst themselves.

This should not be considered as an argument against offering tiered consent in general, but it marks a difference to the conclusions reached based on a concept of descriptive solidarity: Not all real-world preferences deserve the same consideration from an ethical perspective. Existing injustices and potential exclusionary consequences must be kept in mind.

Normative Solidarity

A concept of normative solidarity can be assumed to have a stronger impact on any debate in applied ethics as it directly relates to the value of justice and is conceptualized as a source of moral duties. It still needs to be weighed against other values and duties but it might be shown to be of at least equal, possibly even higher importance. In the context of consent debates, if it can be shown that individuals have a duty to consent to research we have prima facie reason to reject their right to deny consent.

If we assume that individuals have a solidarity-related moral duty in the context of participating in research, what exactly might this duty look like and how does it relate to models of consent? Moral duties are generally considered to be impartial. They are duties we have towards any human being or any bearer of moral rights, not just to some. They might be agent-relative depending on whether we are in a position to fulfil them (the right place, the right time, the right means). But they are generally not an object of choice. If we have duties to support research, we can assume that you and I have at least roughly the same duties. If cancer patients deserve our solidarity, we both have a duty to support the research that can improve their lives. If it is patients with rare diseases that have suffered un-proportionally in the past, we both must be assumed to hold a duty towards them. It should be noted here that a simple reference to a common good is not enough to place such a duty on us. If normative solidarity is necessarily directed at the realization of justice, some injustice must exist to ground our duties of solidarity.

In contrast to the concepts of solidarity discussed above, normative solidarity does not point us in the direction of tiered consent. Either all studies A, B, C and D can be shown to address an issue of injustice—the unjust suffering of humans with an illness where a cure for them could be found. Or only cancer-related research, or research into rare diseases can be shown to actually fulfil this function. Correspondingly, our moral duty to show solidarity would only relate to the relevant studies. Whichever set of studies it is, it is likely the same for all of us and could most easily be covered under a model of some specific version of a broad consent. Note here, that this broad consent might not cover A, B, C and D, but potentially only comprise studies A and C if these are identified as the studies that address a justice-related issue. (This does not imply that the studies B and D should not be conducted. Only that potential participants do not appear to have a moral duty grounded in solidarity to support this research.)

Considering solidarity as a moral duty in the realization of justice might carry us one step further. It can lead us to ask the question on why consent for research must take precedence at all. If in certain cases the needs of those suffering unjustly carry more weight than the interests of those whose samples and data are needed for research, it seems feasible to consider research without consent perfectly legitimate from an ethical perspective. Consent might be needed only where a moral duty to participate does *not* exist. And this conclusion must not appear too troubling, if we remember that the standard of informed consent was originally meant to protect bodily integrity and that in the case of health data research, bodily integrity is not affected. The question of what kind of risks data-based research actually poses to the individual is one of ongoing debate. And in the legal sphere, the GDPR considers consent as only one justification for data-based research among others. General public interest—and public health is named as one possible objective—is considered as an equally valid justification for data processing (Reichel, 2021; Becker, 2022). One might argue that it is only just if everyone contributes equally to public health research—that we have a duty of solidarity to support this. From a perspective of normative solidarity it can also be argued that research targeted at eliminating existing injustices in health care should be added to the list of objectives that justify data processing for research without consent.

The conclusion that out of considerations of normative solidarity consent for health data or biobank research is not needed at all can be rejected in several ways. First, by denying that our duty to support research is strong enough to override other concerns. Second, by pointing out that even if we have duties of solidarity to support research, they might well be understood as imperfect duties: A duty that can be fulfilled in many ways, where consent to research is only one. (Donating a significant amount of money might be another.) Third, by showing that the risks of participation in research are not equal for all and giving broad consent might put a much higher burden on some members of our societies than others. Asserting that we do have a solidarity-based moral duty to support research marks by no means the end of the consent debate.

A challenge inherent to the normative concept of solidarity lies in its relation to justice—and the simple fact that it is often difficult to determine what is just. There might be structural injustices in medical research that are perpetuated by some types of research and countered by others. Researchers, ethics review boards or oversight institutions might be in a position to determine appropriate guidelines and differentiations. Patient representatives might well be given a voice in such contexts but maximizing individual choice in the context of consent hardly appears as the best way to address such injustices.

That a certain perception of given injustices can also lead us away from favouring broad consent can be shown by a short look at the conclusions that Gould draws from her own concept. Gould suggests that solidarity should lead us to reject commercial use of health databases—following in a Marxist tradition, she sees the root of deep social injustices in capitalist economic structures (Gould, 2018).

Considerations of global justice might lead us in yet another direction: It could be argued that as societies of the global north, we invest immense resources into researching expensive treatments of diseases that, on a global scale, are a minor cause of human suffering. And these treatments might never be available to those worst off because of too high cost. A huge portion of human suffering worldwide is due to lack of medical provisions and low standards of hygiene that we have long known how to address—but simply do not, on a global scale. Our strongest duties, then, might be towards those who fall outside of the circle of persons likely to profit from the limited national and multi-national research programmes currently implementing models of broad consent (Binagwaho et al., 2016; Friedman and Gostin, 2017; West-Oram and Buyx, 2017). Taking these considerations seriously, research targeted at improving the health of the overall well-off might only appear permissible once we have satisfied this primary duty.

One could react to these inferences by pointing out that it is potentially wrong to tie normative solidarity to justice in this manner. Are not the needs and interests of those suffering from illness enough to ground a duty of solidarity? I do not think that such a fourth account of solidarity holds much promise. First, it moves the concept away from debates around political solidarity closer to a general idea of duties of welfare. The idea that we have such duties certainly has merit, but it does not seem that they are necessarily related to solidarity at all. Second, such a concept of solidarity would once again have trouble addressing the dark side of solidarity—the concern that in solidary practices the needs of some are considered over the needs of others. This is the core concern that a concept of solidarity as tied to justice attempts to address.

Conclusion

It has been demonstrated that solidarity can be conceptualized in a number of different ways and with a relevant difference to its normative claim. Descriptive solidarity has no normative claim in and of itself. Considerations of descriptive solidarity might appear appropriate to remind us that there are actual patient preferences to be taken into account beyond philosophical ideals of autonomy in debates about consent for non-interventional research. Beyond this, the concept carries little weight in an ethical debate.

The second concept comes with a little more normative impact. It informs us as individuals that we might have good reason to consider solidary action at least occasionally, as it can often contribute to the realization of justice. But again, the concept denies that we have any moral duty to do so. And if we choose to act in solidarity, there are any number of solidary practices open to us. A concept of solidarity of axiological normativity appears suitable to argue for *allowing* and even *encouraging* solidary action through broader forms of consent where no increase in existing injustices due to exclusionary side-effects must be assumed. It does not provide us with any argument to disregard individual preferences for study-specific consent. And as long as no single solidary practice of consent has been shown to be best, tiered consent, not broad consent, appears to be best suited to accommodate multiple solidarities.

The only concept of solidarity that has enough normative claim to potentially override individual interests in the context of consent is one inherently tied to the value of justice: normative solidarity. Only this narrow concept of solidarity is taken to ground moral duties—duties derived from our responsibility to counter injustices. But even this kind of solidarity can only be seen as a justification to limit self-determination where a clear relation to existing injustices can be shown. Standard references to medical research as a good of common interest are not enough to motivate a duty of solidarity in this sense—at the very least, a just distribution of the resulting good would have to be ensured.

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Notes

1 Nevertheless, for an interesting discussion of institutionalized solidarity in health care and its implications for research see (Hoedemaekers et al., 2007).

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References

Becker, D. (2022). 'Die Wissenschaftsprivilegierung in der DSGVO'. *Ordnung der Wissenschaft*, **2**, 103–114.

Beskow, L. M. and Weinfurt, K. P. (2019). 'Exploring Understanding of "Understanding": The Paradigm Case of Biobank Consent Comprehension'. *The American Journal of Bioethics: AJOB*, **19**, 6–18.

Binagwaho, A., Wagner, C. M. and Farmer, P. E. (2016). 'A Vision for Global Cancer Medicine: Pursuing the Equity of Chance'. *Journal of Clinical Oncology*, **34**, 3–5.

Bude, H. (2019) *Solidarität: Die Zukunft einer großen Idee*, München, Hanser.

Budin-Ljøsne, I., Teare, H. J. A., Kaye, J., Beck, S., Bentzen, H. B., Caenazzo, L., Collett, C., D'Abramo, F., Felzmann, H., Finlay, T., Javaid, M. K., Jones, E., Katić, V., Simpson, A. and Mascalzoni, D. (2017). 'Dynamic Consent: A Potential Solution to Some of the Challenges of Modern Biomedical Research'. *BMC Medical Ethics*, **18**, 4.

Bunnik, E. M., Janssens, A. C. J. W. and Schermer, M. H. N. (2013). 'A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing'. *European Journal of Human Genetics*, **21**, 596–601.

Cambon-Thomsen, A. (2004). 'The Social and Ethical Issues of Post-genomic Human Biobanks'. *Nature Reviews. Genetics*, **5**, 866–873.

Campbell, A. V. (2007). 'The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust'. *King's Law Journal*, **18**, 227–245, available from https:// heinonline.org/HOL/P? h=hein.journals/kingsclj18& i=227

Capron, A. M. (2018). 'Where Did Informed Consent for Research Come From?' *The Journal of law, medicine & ethics: a journal of the American Society of Law, Medicine & Ethics*, **46**, 12–29.

Caulfield, T. and Kaye, J. (2009). 'Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas'. *Medical Law International*, **10**, 85–100.

Caulfield, T. and Murdoch, B. (2017). 'Genes, Cells, and Biobanks: Yes, there's Still a Consent Problem'. *PLoS Biology*, **15**, e2002654.

Chadwick, R. and Berg, K. (2001). 'Solidarity and Equity: New Ethical Frameworks for Genetic Databases'. *Nature Reviews. Genetics*, **2**, 318–321.

Friedman, E. A. and Gostin, L. O. (2017). 'From Local Adaptation to Activism and Global Solidarity: Framing a Research and Innovation Agenda Towards True Health Equity'. *International Journal for Equity in Health*, **16**, 18.

Gefenas, E., Lekstutiene, J., Lukaseviciene, V., Hartlev, M., Mourby, M. and Cathaoir, K. (2021). 'Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-Road'. *Medicine, Health Care, and Philosophy*, **25**, 23–30.

Gould, C. C. (2018). 'Solidarity and the Problem of Structural Injustice in Healthcare'. *Bioethics*, **32**, 541–552.

Hansson, M. G., Dillner, J., Bartram, C. R., Carlson, J. A. and Helgesson, G. (2006). 'Should Donors be Allowed to Give Broad Consent to Future Biobank Research?' *The Lancet Oncology*, **7**, 266–269.

Harmon, S. H. E. and Mcmahon, A. (2014). 'Banking (on) the Brain: From Consent to Authorisation and the Transformative Potential of Solidarity'. *Medical Law Review*, **22**, 572–605.

Hoedemaekers, R., Gordijn, B. and Punenburg, M. (2007). 'Solidarity and Justice as Guiding Principles in Genomic Research'. *Bioethics*, **21**, 342–350.

Hummel, P. and Braun, M. (2020). 'Just Data? Solidarity and Justice in Data-Driven Medicine'. *Life sciences, society and policy*, **16**, 8.

Johnson, R. and Cureton, A. (2022) Kant's Moral Philosophy. In Zalta, E. N. and Nodelman, U. (eds), *The Stanford Encyclopedia of Philosophy*, Fall 2022 Edition. Stanford: Metaphysics Research Lab, Stanford University: https://plato.stanford.edu/archives/fall2022/entries/kant-moral/.

Kant, I. (1968) *4. Kritik der reinen Vernunft (1. Auflage 1781)*. Prolegomena [u.a.], 1902nd edn, Berlin: De Gruyter.

Kaphegyi, T., Rhein, P., Sorce, G. and Lehnert, D. (2022) Einleitung. In Sorce, G., Rhein, P., Lehnert, D. and Kaphegyi, T. (eds), *Exkludierende Solidarität der Rechten*. Wiesbaden, Springer Fachmedien Wiesbaden; Imprint Springer VS, pp. 1–18.

Kasperbauer, T. J., Gjerris, M., Waldemar, G. and Sandøe, P. (2018). 'Communicating Identifiability Risks to Biobank Donors'. *Cambridge quarterly of healthcare ethics: CQ: the international journal of healthcare ethics committees*, **27**, 123–136.

Kolers, A. (2020). 'What Does Solidarity do for Bioethics?' *Journal of Medical Ethics*, **47**, 122–128.

Köngeter, A., Schickhardt, C., Jungkunz, M., Bergbold, S., Mehlis, K. and Winkler, E. C. (2022). 'Patients' Willingness to Provide Their Clinical Data for Research Purposes and Acceptance of Different Consent Models: Findings From a Representative Survey of Patients With Cancer'. *Journal of Medical Internet Research*, **24**, e37665.

Lahusen, C. (2020) European Solidarity: An Introduction to a Multifaceted Phenomenon. In Lahusen, C. (ed), *Citizens' Solidarity in Europe*. Siegen: Universitätsbibliothek Siegen, pp. 1–28.

Laitinen, A. and Pessi, A. B. (2015) Solidarity: Theory and Practice: An Introduction. In Laitinen, A. and Pessi, A. B. (eds), *Solidarity: Theory and practice*. Lanham: Lexington Books, pp. 1–29.

Mikkelsen, R. B., Gjerris, M., Waldemar, G. and Sandøe, P. (2019). 'Broad Consent for Biobanks is Best - Provided it is Also Deep'. *BMC Medical Ethics*, **20**, 71.

Neuhaus, C. P. (2020). 'Does Solidarity Require "All of Us" to Participate in Genomics Research?' *The Hastings Center Report*, **50**, S62–S69.

Ploug, T. and Holm, S. (2013). 'Informed Consent and Routinisation'. *Journal of Medical Ethics*, **39**, 214–218.

Ploug, T. and Holm, S. (2015). 'Meta Consent: a Flexible and Autonomous Way of Obtaining Informed Consent for Secondary Research'. *BMJ (Clinical research ed.)*, **350**, h2146.

Prainsack, B. and Buyx, A. (2013). 'A Solidarity-Based Approach to the Governance of Research Biobanks'. *Medical Law Review*, **21**, 71–91.

Prainsack, B. and Buyx, A. (2016) *Das Solidaritätsprinzip: ein Plädoyer für eine Renaissance in Medizin und Bioethik*, Frankfurt: Campus Verlag.

Prainsack, B. and Buyx, A. (2017) *Solidarity in Biomedicine and Beyond*. Cambridge: Cambridge University Press.

Prictor, M., Teare, H. J. A. and Kaye, J. (2018). 'Equitable Participation in Biobanks: The Risks and Benefits of a "Dynamic Consent" Approach'. *Frontiers in Public Health*, **6**, 253.

Reichel, J. (2021) Allocation of Regulatory Responsibilities: Who Will Balance Individual Rights, the Public Interest and Biobank Research Under the GDPR? In Slokenberga, S., Tzortzatou, O. and Reichel, J. (eds), *GDPR and Biobanking*. Cham: Springer International Publishing, pp. 421–434.

Schmale, W. (2017). 'European Solidarity: A Semantic History'. *European Review of History: Revue européenne d'histoire*, **24**, 854–873.

Tranow, U. (2012) *Das Konzept der Solidarität: Handlungstheoretische Fundierung eines soziologischen Schlüsselbegriffs*, Wiesbaden: VS Verlag für Sozialwissenschaften.

West-Oram, P. G. N. and Buyx, A. (2017). 'Global Health Solidarity'. *Public Health Ethics*, **10**, 212–224.

Wiertz, S. and Boldt, J. (2022). 'Evaluating Models of Consent in Changing Health Research Environments'. *Medicine, Health Care, and Philosophy*, **25**, 269–280.

Wiertz, S. and Boldt, J. (2023) 'Ethical, Legal and Practical Concerns of Implementing New Forms of Consent for Health Data Research: A Qualitative Interview Study, JMIR Preprints. 29/08/2023:52180: https://preprints.jmir.org/preprint/52180.

Young, I. M. (2006). 'Responsibility and Global Justice: A Social Connection Model'. *Social Philosophy and Policy*, **23**, 102.