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## **Research Involving Minors—A Duty of Solidarity?**

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**ABSTRACT:** Research without direct medical benefit for the participants raises a number of difficult ethical issues. In particular, it is controversial whether it is ethically justifiable to conduct such research with participants who are unable to give informed consent, in particular minors. One attempt to vindicate such research is based on the concept of group benefit. According to this concept, experiments are justified, even if they do not hold out direct medical benefit for the participants, as long as they can be expected to be beneficial for members of a group that the research subjects are also members of (e.g., the group of minors). In this article, we shall reject the concept of group benefit as a means to justify medical research involving minors. Instead, we suggest an approach that bears on the concept of solidarity, understood as a principle of a moral division of labor that is based on considerations about efficiency in discharging ethical requirements. According to this approach, minors can be under the obligation to participate in research insofar as they are in a privileged position to help overcome an ethically relevant deficit. This is, admittedly, only the case as long as the participation is not excessively demanding. In closing, we discuss some possible objections against this approach.

**KEY WORDS:** research; minors; solidarity; moral division of labor; group benefit; consent; autonomy

## **I. INTRODUCTION**

Ever since scientific experiments have become the methodical standard in medicine during the 19th century, the question whether or under which conditions research involving humans can be ethically justified has been subject to controversial debate. One of the most important principles to justify research on humans is the principle of informed consent: According to this principle, potential research subjects must be informed about all relevant aspects of an experiment in advance. On this basis, they can decide for or against participating in the experiment. An autonomous decision in favor of participation constitutes a strong element in the process of ethical justification. However, it is widely acknowledged that some further conditions must be met. The experiment must, for example, not lead to severe damage to the psychophysical integrity of the research subjects, the foreseeable risks must be adequate when weighed against the expected scientific gains, and the recruitment of the research subjects must meet requirements of justice.

The recruitment of adult research subjects who are able to make an autonomous decision is generally regarded as ethically acceptable. For two reasons, the case of research involving minors is far more complicated. First, the principle of informed consent is not or at least not fully applicable, because minors, especially children, are not fully developed autonomous agents. They often lack the capacities needed to give informed consent. Second, due to their not yet fully developed capacities, minors show a much higher degree of vulnerability. Therefore, Paul Ramsey rigorously rejected the participation of minors in medical research without direct medical benefit for the participants as a “sanitized form of

barbarism.”<sup>1</sup>(p. 28) However, this position has quite problematic implications.

The pediatrician Harry Shirkey coined the phrase “therapeutic or pharmaceutical orphans” as early as in 1963 to emphasize the fact that the development of new medical products and procedures neglects minors.<sup>2</sup> (In this text, Shirkey refers to a conference in 1963 in which he already used the term.) According to Shirkey, the thalidomide catastrophe led to stricter regulations that were supposed to assure the security and effectiveness of drugs developed for minors. However, these regulations had the effect that the supply of drugs for minors changed for the worse. Frequently, drugs were not tested on minors. Yet, testing drugs on minors is necessary to survey their effectiveness and security, as minors show differences in their metabolism that make it impossible to simply transfer the results of research performed on adults to minors.

There have been no significant changes in this situation for the last 40 years. Minors are often treated with so-called “off-label” or “off-license” products, i.e., products that are not licensed for use in pediatrics or the actual area of application. According to Chiara Pandolfini and Maurizio Bonati, between 11% and 80% of prescriptions are “off-label” or “off-license.”<sup>3</sup> Without results from medical research, pediatricians must decide about the use of a certain drug based on their individual experience—and they must decide about dosage without scientifically secured data.<sup>4</sup> Due to this situation, there have been efforts to increase medical research in pediatrics, both in the USA<sup>5,6</sup> and the EU. (For the European Union, the Regulation (EC) no. 1901/2006 of the European Parliament and Council from Dec 12th 2006 is important to mention.)

Nevertheless, it is still a controversial matter whether and under which conditions medical research on minors is ethically justified. One approach that has been developed in recent years is based on the concept of “group benefit.” It is, however, questionable whether this

concept is convincing. In the following, we argue that this is not the case (Sec. II). Subsequently, we present the concept of solidarity as an alternative approach that might be better suited to justify research involving minors (Secs. III and IV). In a final step, we explore the possibilities and limitations that come with the concept of solidarity (Sec. V).

## **II. GROUP BENEFIT AS AN APPROACH TO JUSTIFY RESEARCH INVOLVING MINORS**

A classic distinction in the debate on medical research is the distinction between research that is of direct medical benefit for the participants on the one side and research that is not of such benefit on the other side. Within the latter class, a further distinction has been introduced in recent years, namely, research that benefits members of the same group. Such groups are typically constituted according to facts such as suffering from the same disease, or being of the same age. This distinction gains special significance when applied to research involving minors. A case in point is the European Council who used the concept of group benefit in its *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. According to Article 17, research on persons who are not able to give informed consent to participation in research (including minors) is legitimate if, among other things: The research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition [...].<sup>7</sup>

Furthermore, by now the national legislations of some states incorporate the concept of

group benefit, in particular in the context of regulations regarding research involving minors. (Council of Europe 1997: Art. 17, no. 2(i). The German Medicinal Products Act (Arzneimittelgesetz) mentions in § 41.2.2.a as a special condition for clinical trials involving minors, inter alia, that “the clinical trial must be of direct benefit to the group of patients suffering from the same disease as the person concerned.” Available at: [http://www.bundesrecht.juris.de/englisch\\_amg/index.html](http://www.bundesrecht.juris.de/englisch_amg/index.html) [Accessed 31 Aug 2014].)

Hence, the category of research that aims at benefitting a certain group has increasingly been established as a distinct category in the bioethical debate. However, its adequacy can be called into question. In particular, it is doubtful whether it is possible to uphold the distinction between research that is of no benefit to the participants (and therefore ethically problematic) and research that benefits the participants (either directly or indirectly, making it ethically acceptable) without research that benefits group members falling into the first category. To quote Ramsey again: “A child is not a piece of ‘childhood.’”<sup>1</sup>(p. 28)

Defenders of the concept of group benefit might argue that research involving minors is legitimate due to the lack of alternatives. Here, however, looms a different form of argument, namely, a consequentialist logic of justification that takes the form of a balancing of goods. Several factors are taken into account, such as the risk that is involved in the experiment, the alternatives to research involving minors, and the benefit that can be expected from the experiment, both for the participant and for the group of which the participants are members. Taken this way, group benefit is just one more element to enter that balancing process. Yet, on closer inspection, it turns out that in a purely consequentialist framework the concept of group benefit is either morally problematic or dispensable. If it serves to weigh the benefit of one group more than that of another group, it appears to be morally problematic. Why should the benefit, say, of adults be less

important than that of minors? If, on the other hand, it is supposed to serve to implement a principle of subsidiarity according to which more vulnerable research subjects, say minors, should only be recruited if less vulnerable participants are inappropriate for methodological reasons, then it seems dispensable. It is reasonable to assume that such a principle can be established merely by balancing benefits and burdens.

Finally, group benefit is a descriptive concept. It is a descriptive fact that other members of the group might benefit from the research, but not the participants themselves. From this, it does not immediately follow that such research is justified. Further argument is needed to show that the descriptive concept of group benefit justifies ethical judgments, such as the judgment that it is permissible to perform research on minors who are not fully able to give informed consent.

To sum up, employing the concept of group benefit in order to justify research involving minors seems rather problematic. In one line of reasoning, the concept does not, by itself, carry significant argumentative load. Rather, it is a descriptive concept that can enter a consequentialist balancing process, but it remains unclear whether it has the normative significance that proponents of the concept claim. In another line of reasoning, the concept does carry argumentative load, but reveals significant theoretical difficulties. Hence, the concept of group benefit seems inadequate to solve the problem of justifying research on minors who are unable to give informed consent.

Thus, the question remains how to justify research involving minors. An important aspect of such research is that the research subjects do not benefit from the research, but other members of the group of minors. This suggests that the justification must somehow refer to the group. The concept of group benefit makes such a reference, but it seems to be unsuccessful in justifying the research. Thus, it is worthwhile to consider another ethical

concept that refers to a relevant group: The concept of solidarity.

### III. THE CONCEPT OF SOLIDARITY

Solidarity as an ethical concept has gained increasing attention in the bioethical literature during the last couple of years.<sup>8</sup> Yet, it is a contested concept,<sup>9</sup> insofar as different authors employ the concept in different contexts, without a consensus about the exact implications of the term. One can at least distinguish two basic understandings of solidarity, a descriptive and a normative one. As a descriptive concept, solidarity denominates a mutual feeling of togetherness among members of a certain group. As a normative concept, solidarity implies moral requirements. Thus, members of a solidarity group can demand the performance of certain acts from each other.

In many cases, these two understandings of the term are intertwined. The feeling of togetherness can motivate the very actions that other members of the group can demand. Nevertheless, the two understandings are distinct. If a member of a solidarity group fails to act in the way that other members can demand, these other members of the group are justified in showing reactive attitudes that are typical for the violation of moral demands, such as anger and resentment.<sup>10</sup> This often holds even if the defecting member does not strongly identify with the group—failing to understand oneself as a member of a solidarity group might already be a reason for criticism. And if it is possible to criticize a person who does not exemplify solidarity for her lacking the feeling of togetherness, the two understandings of solidarity are independent of each other—solidarity in the one sense can occur without solidarity in the other sense. Furthermore, given that the reactive attitudes are typical for the violation of moral demands, it seems plausible to understand demands of solidarity as *moral* demands, not merely as demands that stem from some common interest

of the group or its members.

In what follows, we employ the *normative* understanding of solidarity. However, not only is the concept of solidarity as such a contested concept; the same holds for its normative understanding in particular, as there are different understandings of what solidarity in the normative sense implies. In what follows, we propose an understanding of the term that characterizes solidarity by four aspects of the concept that authors typically imply when they use the term. These aspects in combination characterize solidarity as a distinct ethical concept.<sup>11</sup>

First, solidarity implies the aspect of *assistance*. Whenever an agent performs an act of solidarity, she thereby helps another person in achieving some aim. Thus, respecting the bodily integrity of another person normally does not count as an act of solidarity. The assistance might be reciprocal, but that is not necessarily the case. We can easily imagine cases of solidarity in which an agent helps others without getting a similar kind of help in return.

However, pointing this aspect of assistance is not sufficient to characterize solidarity as a distinct ethical concept. After all, altruism also manifests itself in acts of assistance, because an altruistic person helps others to achieve well-being or to further their interests.<sup>12</sup> Yet, as has been noticed by several authors, solidarity is not identical with altruism.<sup>8,9,13</sup> One of the most important differences between solidarity and altruism is that the latter is universal in scope, whereas the former is restricted to certain groups.

This leads to the second aspect of solidarity: The aspect of *group-relatedness*. It is often noticed that solidarity is practiced within specific (solidarity) groups<sup>14–17</sup>: an agent who practices solidarity acts on behalf of a person that is member of the same (solidarity) group as the agent himself. Pointing out this second aspect solidarity obviously leads to the

question of how to characterize solidarity groups. Not every contingent group qualifies as a solidarity group; for example, a random crowd of people waiting at the bus stop does not. The relevant criterion cannot be a feeling of togetherness, because, as was mentioned above, it is possible to demand solidarity even if the agent does not identify with a certain group. Hence, identification with a group is not a constituting factor for the group. Neither is such identification a sufficient condition for the existence of the group. The fact that I strongly identify with the USA does not make me a member of the solidarity group of citizens of the USA, given that I am not an American citizen.

This leads to the third important aspect of solidarity, namely, the aspect of *identity*. Members of solidarity groups share a feature that is (partly) constitutive of their identity, and solidarity groups consist of those persons who share this feature, even if they do not strongly identify with other members of the group.<sup>14,18</sup> Thus, given that waiting for the bus does not constitute a person's identity, the crowd at the bus stop does not qualify as a solidarity group. But what counts as an identity-constituting feature in the relevant sense? To repeat, mere identification is not enough. Even if I strongly identify with the USA, I do not share the feature of US citizenship, and thus I am not a part of that solidarity group. And my German citizenship might be part of my self-understanding and thus of my identity, even if I do not have a strong feeling of togetherness with fellow Germans. The features that constitute solidarity groups must therefore be understood as features that can be ascribed to persons objectively; they describe a person in general terms ("a doctor," "a father," "a compatriot"). In a lot of cases, sharing the feature is a matter of choice, but this is not necessarily the case, as the example of citizenship shows. In this regard, the features that constitute solidarity groups resemble social roles as analyzed by Michael Hardimon.<sup>19</sup>

Finally, in order to characterize solidarity as a distinct *ethical* concept, another aspect is important, namely, what Rainer Forst calls “*normative dependency*.”<sup>20</sup> Acts of solidarity are not justified simply because they exemplify solidarity. After all, it is possible to practice solidarity to achieve immoral ends—the solidarity of Nazis can help to achieve racist aims, but such help is not justified simply because it counts as an instance of solidarity. In order to generate justified demands, solidarity calls for higher-ranked ethical principles. In other words, solidarity is justified if and only if it serves the function of fulfilling ends that are ethically justified. For example, solidarity often aims at overcoming injustice. In such cases, the concept of justice defines an end, and the solidarity of the victims of the injustice is a means to achieve that very end. There might be cases in which concepts other than justice identify the relevant ends, but in any case, the relevant end of justified solidarity is related to the shared feature that constitutes the solidarity group, insofar as it is an ethical deficit that is related to that feature. For example, women may unite in solidarity to overcome sexism. In such a case, the sexism constitutes an injustice that is directly related to the shared feature of the members of the solidarity group (being a woman), and given that no single woman can overcome sexism by herself, solidarity among the members of the relevant solidarity group is called for.

At this point one might object that this characterization of solidarity renders the concept redundant. After all, the ends that solidarity aims to achieve are justified by higher-ranked principles, justice being one example. But clearly, whenever injustice occurs, all moral agents are called to help overcome the injustice. So what does the concept of solidarity add to the higher-ranked principles or concepts that give rise to the specific ends solidarity aims to achieve? Does the talk of duties of solidarity not imply a doubling of duties?

This is not necessarily the case. As one of us has argued elsewhere,<sup>11</sup> solidarity can play an

important role in ethical discourse when it is conceived as a principle of a “moral division of labor.”<sup>21</sup>

The idea of a moral division of labor can be illustrated by Henry Shue’s concept of a distribution of duties. Shue distinguishes two kinds of moral duties: negative duties on the one hand and positive duties on the other.<sup>22</sup> Negative duties are duties “not to deprive people of what they have rights to”.<sup>22</sup>(p. 690) Positive duties are duties of assistance; they are more demanding than negative duties: A duty’s being positive [...] means that fulfilling it will require the expenditure of some resource I control, like time, money, energy or emotional involvement. [...] fulfilling a positive duty may unsurprisingly feel more burdensome than fulfilling a negative one.<sup>22</sup>(pp. 689–90)

Given that duties of assistance imply more cost to the agent as compared to negative duties, and given that, in principle, every agent has duties of assistance to help every needy person, positive duties seem to pose excessive demands on moral agents. Therefore, they “need to be divided up and assigned among bearers in some reasonable way.”<sup>22</sup>(p. 690) Such a distribution of positive duties reduces their demandingness, which helps to discharge them in a more efficient way, as compared to a scenario in which persons try to discharge their duties of assistance in an uncoordinated manner. We understand solidarity as a principle that can be understood along these lines, namely, as a principle that assigns universal duties to individual actors.

Taken this way, duties of solidarity are not redundant. They are general duties assigned to specific persons in order to avoid the potential overdemandingness implied by positive duties. The relevant idea behind a distribution of moral duties is a principle of efficiency— if positive duties are distributed, this helps to discharge them more efficiently, and it is reasonable to take shared features as one factor that helps determine how to distribute

these duties. Given that the moral deficits in question are related to shared features, members of solidarity groups can better detect cases in which help is needed. For example, women might better be suited to detect cases of everyday sexism than men. In addition, they might know better which measures help to overcome the injustice. Thus, members of solidarity groups are in a privileged position to help, and, for that particular reason, are under the obligation to help. Of course, they are only the bearer of a primary responsibility: in cases in which the members of a solidarity group cannot achieve the relevant end by themselves, the duty of assistance is conveyed to other actors who are in a better position to do so.

Even if solidarity implies acting on behalf of other members of a specific group, the concepts of solidarity and group benefit are not identical. Most importantly, group benefit is a descriptive concept. (We thank an anonymous reviewer for the suggestion to emphasize the distinction between group benefit as a descriptive concept and solidarity as a normative concept.) The relevant groups are constituted by contingent factors; however, it is not clear why some action should be justified simply because other members of a specific, contingent group benefit from its performance. Solidarity, on the other hand, is a normative concept that does not rely merely on descriptive factors. After all, not every contingent group counts as a solidarity group, and given that the idea of morally justified ends is part of the concept of solidarity, the problem of justification does not arise in the same way. After all, it is pointless to ask whether a person is morally justified in fulfilling her moral duties. (This, of course, should be read as a claim about prima facie duties—a person might not be justified in fulfilling her moral duties in cases in which these duties are overridden by even stronger duties.) Of course, there might be cases in which the concepts are almost identical. If a person fulfills her duties of solidarity, she thereby benefits other

members of the solidarity group. However, in such cases, it is the concept of solidarity that does the normative work of justification, not the concept of group benefit. Thus, the concepts might yield similar results in certain situations, but that does not mean that they are identical.

#### **IV. THE PARTICIPATION IN MEDICAL RESEARCH—A DUTY OF SOLIDARITY?**

The foregoing considerations are applicable to the problem of justifying medical research on minors. The main line of argument runs as follows:

It constitutes an ethically relevant deficit if persons suffer from a disease (or, more generally, from a health-related disadvantage) that is presently untreatable (or not treatable in an efficient way), but that can be expected to be treated once it has been made the object of medical research. The fact that one can reasonably expect that it will be possible to overcome the deficit generates an ethical requirement to help the affected persons. But the question is who is under the obligation of taking the necessary steps to fulfill this requirement. In other words: who has the primary responsibility to fulfill a certain duty that is, in principle, universal in scope?

This question asks for a justified way of dividing moral labor, and this is where the concept of solidarity becomes relevant. According to this concept, considerations of efficiency play a crucial role in identifying the duty-bearers. In the case of minors suffering from health-related disadvantages, the necessary steps to provide the help consist in performing medical research in order to develop drugs. Here, other minors are in a privileged position to help, because they are the only ones who can help gather the necessary data through medical

research. This puts them under a specific obligation which can be described in terms of solidarity, since minors share a specific descriptive feature that forms an important part of their self-description (“being a minor”), and the ethically relevant deficit in question is directly linked to this feature. After all, they suffer from a health-related disadvantage for which no drugs have been developed because research has not yet been performed on minors, whereas there might be drugs developed for adults who suffer from the same disease which cannot be used on minors. Thus, the fact that there are no drugs available for the minors is due to their status as minors. By participating in medical research, minors help other members of the specific solidarity group (the group of minors) to overcome a deficit that is linked to the shared feature which constitutes the group. According to the solidarity approach as developed here, minors therefore have a duty of solidarity to participate in medical research, and this duty is moral in nature. This justifies such research, as being justified is implied by the concept of a moral duty.

It is important to emphasize one point. Part of the rationale to develop the concept of a moral division of labor is that it avoids overdemandingness. From this, it follows that duties of solidarity must not be overdemanding themselves; after all, the whole point of a moral division of labor is to reduce demandingness, not to increase it.<sup>22</sup> One example for overdemandingness is participation in an experiment that puts a significant risk on the research subjects. There is no duty to participate in high-risk medical research, and the concept of solidarity cannot justify such research when performed on minors.

This in turn implies another important feature of the solidarity approach as developed here: a sufficiently low risk for the research subjects alone does not carry any argumentative weight. If there is significant risk for the research subjects, there is no duty to participate in the research. However, it does not follow that a sufficiently low risk grounds a duty to

participate. Considerations about risk serve as a limiting factor insofar as they indicate when a moral requirement is overdemanding and therefore ceases to be a duty, but they do not ground duties. (The same holds for considerations of efficiency. The mere fact that participating in medical research is an efficient way to develop drugs is not sufficient to ground a duty to participate in such research. Other normative considerations are necessary to ground a duty. The concept of solidarity is as a concept that provides such additional normative considerations, most importantly the considerations of identity-constituting features that specify which groups give rise to duties of solidarity, and the general framework of a moral division of labor. Hence, even if duties of solidarity rely on considerations of efficiency, the concept of solidarity is not identical with such considerations of efficiency.) Therefore, considerations about risk have a completely different status in an approach that employs the concept of solidarity than in an approach that invokes the strategy of a balancing of goods.

A short comparison of the solidarity approach with a balancing goods approach help to illustrate this. We take the approach of Loretta Kopelman as a contrast foil to our approach. Kopelman distinguishes between two forms of argumentation regarding the justification of research on minors, the “non-consequentialist strategy” and the “consequentialist” or “balancing strategy”.<sup>23</sup>(p. 746) According to her, examples for the former are restrictive regulations that put great limitations on research with minors, such as the *Nuremberg Code* or the *Declaration of Helsinki* of the World Medical Association,<sup>23</sup>(pp. 747–8) whereas cases of the latter are the guidelines of the Council for International Organizations of Medical Sciences (CIOMS) and the regulations in 45 CFR 46. These guidelines follow a consequentialist logic. The balancing of goods takes the minimal risk for the research subjects as well as the expectable scientific progress into consideration and

gives greater weight to the latter. As long as other requirements are met (such as the assessment of an ethics committee and the representative consent of the parents), no further justification is needed.

Kopelman sees the “non-consequentialist strategy” that allows research on minors only in cases in which the research subjects benefit directly from their participation as an implausible “extreme view” that should be rejected. The same holds for the second “extreme” position that sees considerations about risk that apply in cases of informed consent as applicable in cases in which such consent cannot be given.<sup>24</sup>(pp. 89–90) Furthermore, Kopelman rejects a “crude utilitarianism” that is directed solely on the maximization of overall utility, thus putting no regulations concerning risk on medical research with minors.<sup>23</sup>(pp. 757–8) Kopelman herself favors a rule-utilitarian approach, which acknowledges the fact that research on minors is embedded “in a context of deontological or non-negotiable duties.”<sup>23</sup>(p. 760) In this approach, the concept of minimal risk does not play the role of a negative indicator as it does in the solidarity approach but rather serves the function of a justificatory element. With the solidarity approach, however, considerations of sufficiently low risk have no such justificatory role.

We would also like to compare the solidarity approach as developed here with Barry Lyons’s approach that also employs the concept of solidarity.<sup>13</sup> This comparison illustrates the character of solidarity as a contested concept, as Lyons understands solidarity differently than we do, and thus comes to other conclusions.

Lyons differs from our view in two important regards. First, he understands solidarity as identification of an agent with other members of a solidarity group; second, he rejects the idea that solidarity grounds moral duties.<sup>13</sup>(pp. 370–373) Thus, Lyons understands solidarity as a concept that explains the motivation of minors to participate in medical

research. We agree that identification with other members of a solidarity group can be a strong motivational factor. However, we maintain that it is not possible to reduce the ethical concept of solidarity to its motivating force. As argued above, we hold persons responsible when they fail to exemplify solidarity, and the according reactive attitudes suggest that it constitutes the violation of a moral obligation. Furthermore, it is not clear whether an understanding of solidarity as a motivating factor can actually justify research involving minors, as it seems to reduce the function of solidarity to an explanation of why minors might in fact give consent to their participation in medical research. But then the approach suffers from the same problems as informed consent approaches when applied to minors. However, the solidarity approach as developed here can justify research involving minors: if one can plausibly defend the claim that there is a moral duty to participate in such research, one thereby gives an ethical justification for such research.

## **V. THREE POSSIBLE OBJECTIONS**

In this last part of the paper, we want to discuss possible objections against our view: the objection from moral agency, the objection from uncertainty, and the objection from enforceability.

The objection from moral agency claims that, just as it is not possible to simply transfer the results from research on adults to minors, it is not possible to simply apply moral obligations of adults to minors. Children are not moral agents in the same way as adults, and this might raise doubts whether they are duty-bearers in a conception of a moral division of labor as sketched above.

This objection, as important as it is, can be answered within the solidarity approach. We usually do not apply the same ethical standards to children that we apply to adults, but it

does not follow that we see children as not having to meet any ethical requirements whatsoever. Instead, we see children as moral subjects that must meet certain moral requirements, which, of course, take the physical and psychological constitution of children into account. (For example, we expect children not to hit other children in their kindergarten class, and we expect them to share their toys with their siblings.) The objection therefore does not show that children are not dutybearers within a system of a moral division of labor. It merely shows that it is necessary to respect certain conditions of children when allocating responsibilities (when making considerations about justifiable risk, for example). This consideration is similar to one that is presented by Harris and Holm in their strategy to justify research involving minors.

Harris and Holm argue *for* a duty to participate in certain experiments on humans. In their view, the question whether such a duty exists is too general a question to be answered out of a specific context.<sup>25</sup>(p. 123) However, if the research project's overall design is of high quality and if, furthermore, one can expect that the project will lead to important insight that will help other persons in the future, then it is possible to defend a duty to participate in that research. They present different arguments in order to justify such an obligation. First, according to them, such an obligation follows from the "basic moral obligation to help other people in need (or our duty of beneficence)."<sup>25</sup>(p. 124) Second, the obligation can be derived from a "standard Rawlsian, free-rider "argument": we all are beneficiaries of scientific research that has been done in the past, and it would be a form of unfair free-riding if we would use that benefit without supporting further scientific progress.<sup>25</sup>(p. 125) Furthermore, and most importantly in our context, Holm and Harris view minors as moral actors. They have moral rights and can make ethical claims, but they are also bearers of moral duties, participating in (certain forms of) scientific research on humans being one

of them. They conclude:

If a parent does not take this into account when making decisions for the child that parent displays one of the following attitudes; either the attitude that the child is not (and need not be) a serious moral agent at all, or the even more problematic attitude that the child is so deeply fallen in moral turpitude that it is not willing to discharge any of its moral obligations.<sup>25</sup>(p. 125) This shows that Holm and Harris affirm the idea that minors are under certain moral obligations, even if they do not refer to the notion of solidarity to explicate the moral obligation of minors to participate in research.

The objection from uncertainty claims that medical research is a process that is performed over a long period. This means that not only might the research subjects not directly benefit from their participation, but that possibly no actual (living) persons may benefit from it. Only future persons may be the beneficiaries. This, actually, is a problem for a solidarity approach that rejects the concept of group benefit by employing the framework of normative individualism, according to which moral obligations are owed to actual persons. This problem cannot be answered in this paper, as it requires further investigation. What we tried to do is to provide an outline of a new strategy of justifying research involving minors, based on the moral obligation of minors to participate in medical research. And the notion of solidarity seems to be better suited for this task than the concept of group benefit. Whether it is possible to give a convincing justification based on the notion of solidarity to carry out research involving minors that cannot be expected to have medical benefit for any living persons must remain an open question, at least for now.

The objection from enforceability might be the most important one against our approach. It claims that even if minors have a duty of solidarity to participate in medical research that

benefits other minors, this does not show that such research is justified. (We thank an anonymous reviewer for pressing us on this point and for providing the following example.) Research involving non-consenting minors is tantamount to enforcing a moral duty; however, not all moral duties are enforceable simply qua being moral duties. One might draw an analogy to cases of saving children from drowning: an experienced swimmer has a moral duty to save a child from drowning if the risk is sufficiently low, but it is doubtful that we are justified in pushing the swimmer into the water to force him make the rescue. Furthermore, it seems unjustified to perform medical research on non-consenting adults, even if one holds that adults have a moral duty to participate in such research.

Several things can be said in response. First, we understand the stringency of a moral duty – and hence, its degree of enforceability – as a function of two factors, namely, urgency and demandingness. Urgency includes the severity of the situation that gives rise to the duty, but also the number of other potential helpers and the dependency of third parties on the fulfillment of the duty. Demandingness consists in the potential cost to the agent. Demandingness comes first when deciding whether a duty is enforceable: if an action implies too much cost to the agent, the duty is not enforceable. If, in contrast, the cost is sufficiently low, the duty might be enforceable, given a sufficiently high urgency. Applied to the case of research involving minors, one might say that the cases of research involving non-consenting minors and research involving non-consenting adults are different in an important respect. While at present there are enough volunteers to participate in research involving adults, this is not the case with research involving minors. This difference can explain the fact that we do not enforce the moral duty of adults to participate in medical research: given that there are enough volunteers, there is no sufficient urgency to enforce such a duty of non-consenting adults. However, things might be different should there not

be enough adults volunteering in research that involves sufficiently low risk for the participants. In such a case, we might think that it is justifiable to enforce this duty, although this is a matter of speculation.

However, in the case of the swimmer and the drowning child, urgency is high and the risk is relatively low. Hence, the question is whether the swimmer's duty to save the child is enforceable. We think that the swimmer *does* have such an enforceable duty to save the drowning child, even though pushing him into the water might not be an appropriate way to enforce this duty. Intuitions might differ here, but at least according to some legal systems, the swimmer is liable to prosecution if he does not make an effort to save the child. Of course, there are legal systems that would not hold him accountable; we think that this difference mirrors the opposing intuitions in this case. Anyhow, the fact that there *are* some legal systems holding him accountable if he does not try to fulfill his duty suggests that at least it is not unreasonable to think that the swimmer has an enforceable duty to save the child, where enforcing the duty might consist in legal consequences if he fails to act accordingly.

One last point is important. There seems to be a difference between "not being able to consent" and "withholding consent." In fact, we might be reluctant to claim that we are justified in pushing the swimmer into the river because we think that he is withholding consent to save the child.

Arguably, the autonomy of an agent is such an important good that enforcing moral duties of agents who explicitly withhold consent appears problematic in many cases. It might even turn out that the value of acting in accordance with one's duties depends partly on the agent voluntarily fulfilling his duties, although we leave this point open here. The

distinction between not being able to give consent and withholding consent suggests, however, that a duty to participate could be enforceable in cases in which a minor is not able to give fully informed consent. (A further differentiation may be needed at this point: “Not being able to give consent” may mean that a minor is not capable of expressing his will in a relevant sense. In this case, including him in the research would be an act of enforcement, even if the participation is not against his will, i.e., he is not overtly opposing. If, however, a minor gives his assent to participate in a research project—in contrast to a full-blown consent—he would still fall in the category of “not being able to consent,” but the notion of enforcement could seem mistaken. In fact, in this later case the minor is explicitly in favor of participation, but not in the (legal) position to articulate his consent.) Such cases differ from those in which a minor is explicitly withholding consent. For example, if a child is scared of participating in medical research and clearly expresses her wish not to do so, it seems less clear that it is justified to enforce her duty of solidarity. We might describe these later cases as ones in which the relative demandingness of her participating in the research increases to a degree that the duty is not enforceable any longer.

## REFERENCES

1. Ramsey P. *The Patient as person: explorations in medical ethics*. 2nd ed. New Haven: Yale University Press; 2002.
2. Shirkey H. Therapeutic orphans. *J Pediatr*. 1968 Jan;72(1):119–20.
3. Pandolfini C, Bonati M. A literature review on off-label drug use in children. *Eur J Pediatr*. 2005 Sep;164(9):552–8.
4. Henze G. Dose finding in pediatric patients. In: Venitz J, Sittner W, editors.

Appropriate dose selection—how to optimize clinical drug development. Berlin: Springer; 2007. p. 111–21.

5. Field MJ, Behrman RE, editors. Ethical conduct of clinical research involving children. Washington, DC: National Academic Press; 2004.
6. Ross LF. Children in medical research: access versus protection. Oxford: Clarendon Press; 2006.
7. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. European Treaty Series No. 164. Council of Europe; 1997 [cited 2015 Oct 15]. Available from: <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168007cf98>.
8. Prainsack B, Buyx A. Solidarity in contemporary bioethics—towards a new approach. *Bioethics*. 2012;26(7):343–50.
9. Saunders B. Altruism or solidarity? the motives for organ donation and two proposals. *Bioethics*. 2012;26(7):376–81.
10. Strawson P. Freedom and Resentment. *Proc Brit Acad*. 1960;48:1–25.
11. Löscke J. Solidarität als moralische Arbeitsteilung. Münster: Mentis; 2015.
12. Nagel T. The possibility of altruism. Oxford: Clarendon Press; 1970.
13. Lyons B. Solidarity, children and research. *Bioethics*. 2012;26:369–75.
14. Rorty R. Contingency, irony, and solidarity. Cambridge: Cambridge University Press; 1989.
15. Heyd D. Justice and solidarity: the contractarian case against global justice. *J Soc Philos*. 2007;38:112–30.

16. Bayertz K. Four uses of 'solidarity.' In: Bayertz K, editor. *Solidarity. philosophical studies in contemporary culture*. Amsterdam: Kluwer Academic Publishers; 1999. p. 3–28.
17. ter Meulen R, Wright K. Family solidarity and informal care: the case of care for people with dementia. *Bioethics*. 2012;26:361–8.
18. Honneth A. *The struggle for recognition. the moral grammar of social conflicts*. Cambridge: Polity Press; 1995.
19. Hardimon MO. Role obligations. *J Philos*. 1994;91:333–63.
20. Forst R. *Toleration in conflict. past and present*. Cambridge: Cambridge University Press; 2013.
21. Nagel T. *Equality and partiality*. Oxford: Oxford University Press; 1991.
22. Shue H. Mediating duties. *Ethics*. 1988; 98:687–704.
23. Kopelman LM. Children as research subjects: a dilemma. *J Med Philos*; 2000;25:745–64.
24. Kopelman LM. When is the risk minimal enough for children to be research subjects? In: Kopelman LM, Moskop JC, editors. *Children and health care. moral and social issues*. Dordrecht: Kluwer; 1989. p. 89–99.
25. Harris J, Holm S. Should we presume moral turpitude in our children? *Theor Med Bioeth*. 2003;24:121–9.