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ARTICLES

Clarifying Vulnerability: The Case of Children

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Abstract

We agree that vulnerable persons should be afforded additional attention or protection. Attempts to define who is vulnerable and what protections are required have, however, led to multiple accounts which often fail to clarify the issue in practice. This article reviews the different versions of vulnerability found in the literature. It then illustrates, through the example of children, how the application of a version devised for application in research and healthcare serves to clarify the identification and protection of vulnerable persons. In this approach, protecting the vulnerable requires a diagnostic approach. It requires that we identify morally protected interest, situations where they are fragile, the reasons why, and those involved in a duty of protection. In the case of children, the fact that parents are expected to act as their child's protector adds a step to this analysis. Any circumstance that makes parents less likely to be either act as protector or to be effective in protecting a child will compound the vulnerability of this child.

Keywords: vulnerable, child, duty of protection, healthcare, research

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Introduction

From the perspective of bioethics, vulnerability begins with a basic consensus. We generally agree that vulnerable people have a right to protection or special attention. This consensus, which is central in the clinical management of weakened or marginalised persons, is taken up by international texts that often deal with the protection of vulnerability as a minimum requirement. The World Health Organization's *Health for All Policy Framework* provides an example: "Health policies built on concern for justice will ensure that health care are fairly distributed among the population. This means that priority is given to the poor and other socially marginalized and vulnerable groups."[1]

Protecting the vulnerable, then, is recognised as important, but who is vulnerable and what protections are needed? Here, the consensus ends. This article reviews the different versions of vulnerability found in the literature, briefly summarises the case for a definition proposed and defended by the author elsewhere, and illustrates with the example of children how its application serves to clarify the identification and protection of vulnerable persons.

Case Example

A 10-year-old girl is brought by her mother to the emergency department with a history of a sore throat and fever for three days. She suffers from cerebral palsy due to a complicated birth, and has never been able to walk unassisted or to communicate more than a few words. Because examining her can be difficult, her mother has grown accustomed to ER visits often becoming prolonged and does her best to avoid them. When the girl began to run a fever the previous day, her mother waited to see if she would get better and started giving her paracetamol, but is now getting worse. On admission, doctors fear that repeated doses may have led her to ingest a toxic level over the previous 24 hours.

Versions of Vulnerability

The patient described in the vignette above would probably be generally described as vulnerable by almost everyone. But why? In the literature, there are five versions of the vulnerability.[†]

[†] This section is based on an earlier paper published in French by the same author. S. Hurst, "Protecting Vulnerable Persons: An Ethical Requirement in Need of Clarification" [Protéger les personnes vulnérables: une exigence éthique à clarifier], *Rev Med Suisse* 9, 386 (2013): 1054–7.

The first is human finitude. Vulnerability in this sense is a fundamental characteristic of human beings: we are interdependent, fallible, capable of suffering, mortal.[3–5] This notion is, of course, important. Were we not vulnerable in this sense, our moral life would no doubt be very different. Medicine may have little reason to exist at all. This form of vulnerability, however, because it is common to all human beings, cannot provide grounds to identify persons requiring special protection.

The second is an incapacity to defend one's own interests. In this version, persons are considered vulnerable if they are incapable of giving free and informed consent, or if they are more likely to be exploited.[6] In our case, the patient is certainly incapable of decision-making, and children are often considered to be vulnerable on this basis. However, it seems simplistic to limit his vulnerability to this element.

The third version of vulnerability is fragility. Here, vulnerability is viewed as a greater risk of injury or physical or mental harm.[7] Etymologically, vulnerability denotes the ability to be hurt. It clearly applies to our clinical case. Again, however, this is not enough: how should we think about situations where we place ourselves at risk of injury? Some freely choose to place themselves at risk; should we identify as vulnerable anyone who—even freely—makes a choice that is deleterious to their own health?[8]

In the fourth version, vulnerability is viewed as resulting from barriers to health. Persons are considered vulnerable if their access to care is limited, or if their chances for good health are limited.[9] This definition may be applicable to our patient in the above case example. Clearly, however, lack of access to healthcare is not the whole story when it comes to her vulnerability.

In a fifth version, some abandon the goal of providing a view of vulnerability altogether and consider whoever is on a list of vulnerable populations or persons to be vulnerable. Different lists have thus been compiled, mostly in research ethics guidelines.[10, 11] Children are always included in such lists. However, some are so extensive that it becomes unclear if anyone can truly be considered as not particularly vulnerable.

In effect, none of these definitions adequately captures cases where particular vulnerability might exist. For this reason, we propose a sixth version which, in our view, illustrates how previous views of vulnerability all capture a part of the same concept. First, it seems important to distinguish general vulnerability, common to all and rooted in our common biology, and the special vulnerability that underpins requirements for additional protection.[12] This special vulnerability we propose to define as an increased probability of being wronged,[13] or of having our morally protected interests unjustly considered.[12] This applies to any form of wrong, to any morally protected interest, and to any reason why these interests may be unjustly taken into consideration or thwarted. This means that there are many ways in which we can be vulnerable. Rather than being “rivals”, the definitions presented in the literature can be viewed as complementary dimensions of the same vulnerability.

Diagnosing Vulnerability

This form of vulnerability is not an intrinsic attribute of specific persons or populations who might be stigmatised if they were to be viewed as vulnerable *per se*. In one way or another, in different circumstances, we all become vulnerable to some forms of wrongs. In our case example, our patient is vulnerable in several ways at the same time. She is a child, incapable of taking self-determined actions and limited from birth in developing such ability. Her mother’s previous negative experiences with hospital contact limit her access to timely care. She is now at risk of serious physical harm, due to a possibly toxic drug overdose.

Understanding vulnerability as an increased risk of incurring a wrong requires a diagnostic approach in specific cases. In this approach, no one is especially vulnerable *per se*. We can, however, all become particularly vulnerable *to* a given wrong at a given time for different reasons. Protecting the vulnerable will thus require that we identify the wrong a person is vulnerable to, the source of this vulnerability, suitable safeguards, and those who share responsibility for protection. In a first step, wrongs that can occur in a given setting, such as a study protocol or a healthcare programme, should be identified. For example, in a research study requiring informed consent, one possible wrong would occur if participants were recruited without adequate consent. In a second step, any potential participant who is predictably more at risk of incurring this wrong should be identified. In the case of emergency research, for example, even adults who are fully capable of decision-making are more likely than others to be recruited without adequate consent. There is little time for reflection, and thinking through the issues related to research participation while undergoing emergency care can be overwhelming. Those recruited during emergency care are thus particularly vulnerable: they are at increased likelihood that their morally protected interest for self-determination will be unjustly taken into consideration, and the reason is that the circumstances make reflection more difficult while allowing insufficient time. The next step is to devise suitable safeguards. In this case, risk can be minimised by splitting consent for those parts of the study that must be conducted without delay (e.g. recruitment), and those parts of the study that can be deferred to a later time when the participant will be in a better situation to make an autonomous choice. Since there is still some added risk that she will be enrolled in research she would have refused if given time to reflect, additional protection can be provided by giving veto power to a clinician unaffiliated with the study and whose specific task will be to prevent her recruitment if it is against her interests.

This example illustrates several points. First, this approach allows protections to be tailored to specific set of cases. When added to more general protections, such as the requirement that research with vulnerable persons target the health needs of persons like them, and that it should only be conducted if similar results cannot be obtained through the recruitment of less vulnerable persons, such tailored protection represents an improvement. In some cases, these more specific protections may even be superior to the more generic ones. Generic protections often imply a risk of excluding vulnerable persons from research. This excludes them from risks, but also from benefits. It further excludes entire groups from the possibility that research results will be generalisable to them. If sufficiently strong specific protections can be devised to include vulnerable persons in research with appropriate guarantees that such protections will be applied, it may be morally superior to their exclusion. This problem is, of course, relevant in the case of children. They are often excluded from research, and this results in high off-label prescription in clinical care.[14, 15]

Second, protections will sometimes require that several, rather than a single measure be taken. The goal is not to "check the box" indicating that a protection has been provided. Rather, it is to provide credibly effective protection against the transgression of a morally protected interest. Third, protections will sometimes be imperfect. This is the case in our example. Although participants recruited during an emergency will undergo only a part of the study interventions initially and will be able to withdraw consent at a later time, and despite the protection against harm provided by an independent clinician, recruitment still takes place without the possibility of a truly free and informed initial decision. Arguably, a research ethics committee would accept such a study if the research question was sufficiently important to improve care in the sort of emergency setting where patients are recruited. This judgement, however, ought to be firmly in the domain of ethics review. Protocols should thus include a description of the steps outlined here, including the protections which are planned, and explain why the investigators believe recruitment of vulnerable persons in the specific study to be justified.

To understand vulnerability in research and healthcare, then, we must start from an understanding of the morally protected interests.[13, 16] It is when these are at greater risk of being transgressed or unjustly taken into consideration, that particular vulnerability exists.[12] What, then, are the morally protected interests relevant to research and healthcare? In the case of research, ethical principles underpinning the morally protected interests of participants are summarised chronologically as: collaborative partnership; social value of research; scientific validity; a favourable risk-benefit ratio; fair recruitment; independent review; informed consent; and respect for participants.[17] In healthcare, we propose that a list of morally protected interests for patients include: physical integrity; autonomy; freedom; social provision; impartial quality of government; social bases of self-respect and communal belonging.[16] There is, however, less overall consensus as regards healthcare than in the area of research. Some morally protected interests form a "core" over which a great degree of consensus exists, while others are more controversial.

Clear Cases

Diagnosing vulnerability in research will start from those interests of human participants which are clearly recognised as morally protected.[17] Since morally protected interests of research participants are mostly clear, they can serve as a basis to delineate situations where vulnerability exists in the context of research participation. Children are clearly considered to be vulnerable research participants. An outline of sources of vulnerability for children in research is presented in Table 1. The most visible reason is that many are too young for decision-making capacity, and thus unable to give informed consent for their own participation in research.[10] In addition, children who are capable of decision-making are sometimes in a situation of subordination to their parents such that autonomous consent is not possible for them.[18] It has also been argued that children may be among the groups whose interests are at risk of being disvalued.[18] They are seldom in a position to defend themselves from the risk of harm; therefore a more conservative estimate of benefits and a broad estimate of harms should be applied and burdens minimised whenever possible.[19, 20] Moreover, children may be excluded from research participation due to the requirements for further protection they bring into a protocol, and thus excluded from the social value of research.[21] Protections include the adaptation of protections whenever concerns specific to children require an adjustment in order to effectively apply benchmarks for ethical research to them.

Diagnosing vulnerability in healthcare is more difficult, as there is a lesser consensus on what the morally protected interests of patients comprise.[16] It is, however, possible to outline some interests about which there is no real doubt. Three examples of interests clearly considered to be morally protected in healthcare

Table 1. Vulnerabilities of Children in Research

Benchmarks*		Sources of vulnerability
Collaborative partnership		
Social value	Parents able and willing to protect interests of the child	– Children's interests may be disvalued in setting research priorities.
Scientific validity		
Favourable risk-benefit ratio		– Lasting damage can last longer and have a greater impact on life chances. – Children's interests may be disvalued in study design – Children are seldom in a position to defend themselves from the risk of harm.
Fair recruitment		– Children are at risk of being excluded from research altogether.
Independent review		
Informed consent		– When they are too young and lack decision-making capacity, children cannot give informed consent. – Even older children may be in a situation of subordination to their parents and not free to make autonomous decisions.
Respect for participants		– Confidentiality is more difficult to protect in adolescents.

Source: Emanuel et al.[17]

are shown in the upper part of Table 2. Typically, the "core" of patient rights includes: access to care within certain limits (which will, in their turn, be controversial); autonomy, which implies self-determination for decisions affecting our health and our intimate sphere; and confidentiality. This is not a complete list of morally protected interests in healthcare, and in this way the table is incomplete. Other examples could include an interest in maintaining our family ties when we are treated within a health system. In this case, having a rare disease requiring care away from home could be a source of vulnerability.

More generally, if any of our morally protected interests is fragile or threatened, then there is vulnerability. The same morally protected interest can of

Table 2. Examples of Vulnerability in Healthcare

Examples of vulnerability		
Examples of morally protected interests	Example of sources of vulnerability	Data
Access to healthcare	Poverty, minority status	Substantial barriers to access have been documented for children.[26] Correcting them can require considerable efforts.[27]
Self-determination	Cognitive impairment	Underestimation of decision-making capacity by health professionals in assisted living for the elderly.[28]
Confidentiality	Adolescence	Important variation in respect for confidentiality of adolescents who are capable of decision-making in Spain[29] and in the US.[30]
Access to the conditions of health	Marketing of unhealthy choices	Advertising for tobacco,[24] alcohol,[31] and food is effective among minors.[25]
Being in good health	Lower socio-economic level	Correlation between health and eight of its sub-domains, and socio-economic level.[32]

course be threatened by different mechanisms, and the table is thus incomplete in this way as well. The morally protected interests presented in Table 2 are examples, as are the causes of their possible fragility. The column on the right shows examples of data in the literature, but in a clinical situation it is of course also possible to identify fragility in a morally protected interest, and thus vulnerability, on a case-by-case basis. Protections will need to be tailored to the fragile interest, to the source of vulnerability, and to the circumstances where vulnerability arises.

Controversial Cases: A Requirement for Consistency

Some interests relevant to healthcare are not so clearly morally protected. The second half of Table 2 outlines interests of this kind. For example, although we clearly have an interest in being healthy, the degree to which it is a morally protected interest is controversial. In the case of adults, a growing focus on personal responsibility for health tends to deny that an interest in being healthy is morally protected.[22] This does not mean that there is consensus on the lack of moral protection for health itself.[23] However, it does mean that we should expect disagreement on whether someone could be considered vulnerable on the grounds that their health was more difficult to maintain or protect. In the case of children, it will be clearer than in adults that individuals cannot be held responsible for their own health.

Similarly, there is controversy regarding the degree to which we have a morally protected interest in having access to the conditions of health. On the one hand, we clearly have a morally protected interest that our health should not be actively harmed by others. On the other hand, the extent of what we mean by active harm is often unclear. Pouring poison into someone's tea without her knowledge clearly qualifies. Selling cigarettes, which supposedly involves a free choice by an informed buyer, is not similarly considered. Here, rather, it is the freedom to buy or not, and the information on which this choice is made, which constitute the conditions of health. Banning the sale of tobacco to children is predicated on the consideration that children will lack one or both of these conditions. Thus, selling tobacco is not considered to be active harm, but there is agreement here on some degree of protection since children who lack the conditions for making a healthy choice are prevented from making an unhealthy one. Moreover, advertising for tobacco cannot be targeted at children, although data suggests that existing marketing is nevertheless effective among them.[24] Further along the continuum, selling unhealthy food and drinks to children is not banned. Since children are neither more free nor better informed to decide whether to buy sweets or cigarettes, the most plausible explanation is that the difference lies in the different degrees of harm involved. How much harm, then, is too much? Answers here will predictably vary and lead to controversy, especially in a context where some of the unhealthy choices involved are actively—and successfully—being marketed to children.[25]

When controversy exists regarding the existence of an interest—on whether it is morally protected, and on the degree to which it ought to be so—then we should expect disagreement on whether it ought to be included in this approach of vulnerability. At a minimum, however, we can require consistency: recognising that an interest exists and that it is morally protected implies that we also ought to recognise the patterns of vulnerability associated with it. If we do not recognise the interest in question, we will of course not include it in the application of vulnerability. It would be contradictory, however, to recognise an interest as morally protected on the one hand, and on the other hand to exclude it in the application of vulnerability.[16] In this approach, vulnerability is ultimately nothing more than the recognition that there are situations where fulfilling morally protected interests is predictably more difficult.

Parents as a Source of Vulnerability for Children

In considering the vulnerabilities of children, there is often an implicit assumption that parents will be the primary proxies for young children. This role is not limited to substituting informed consent: through this role, parents are also expected to protect their children's interests more generally. In research, they are expected to weigh the risks and benefits, whether the importance of the research question warrants participation of their child, and how their child is likely to be respected in the conduct of research at a particular institution. Parents are viewed as the primary protectors of their children. As shown in Table 1, the assumption associated with the vulnerability of children is that it signals the vulnerabilities that remain after normally able parents have fulfilled their role as their children's protector.

This, however, means that any circumstance that makes parents less likely to be effective in protecting their children will compound the vulnerability of this child. In some circumstances, parents are unable to protect their children's interests because they lack the resources which would be required to do so and that are available to other parents. Uninsured children of parents who are poor, for example, may have little alternative to research participation in order to obtain care even though an alternative treatment may be in their child's best interests.

In other circumstances, parents may not act in their child's best interest although they could. They may place the interests of the child's siblings, or their own personal interests, above that of the child. If an entire family is affected by a serious genetic disorder, parents may consent to risky research participation for one child with an eye to benefits for other family members. In healthcare, they may select a treatment alternative more convenient to them rather than in the best interest of their child. In all such circumstances, children can be placed in a situation of compound vulnerability when their primary protector fails to protect them to the level that can usually be expected. More generally, disenfranchised or marginalised parents will have less ability to protect their children:[18] in addition to their own sources of vulnerability, these children are thus likely to partake of whatever vulnerability would also have affected their parents in a similar situation. In the case of children, fulfilling our duty to protect vulnerable persons requires that we take this dimension into account. In some cases, it should be expected that the most effective protection for vulnerable children will be indirect and aims to either improve the ability of parents to protect their children's interests or to provide children with an alternative primary protector.

Conclusion

From the perspective of bioethics, vulnerability is an important concept, but it is often used too vaguely. If we focus on vulnerability as a requirement for additional protection, then it is useful to understand it as attached to persons when they are at an increased risk of incurring a wrong. Vulnerability in this sense is not an attribute of individuals or of specific groups as such. It is an attribute of individuals within specific circumstances. Thus, there are multiple sources of vulnerability. Because it is attached to circumstances as well as persons, vulnerability is not a stable attribute of persons. At some time or other, we can all be particularly vulnerable to some wrong for different reasons.

Protecting the vulnerable in research and healthcare therefore requires a diagnostic approach: it requires that we identify the morally protected interest that is fragile, the reasons why it is so, and those involved in a duty of protection. Since morally protected interests of research participants are mostly clear, they can serve as a basis to delineate situations where children are vulnerable in the context of research participation. Diagnosing vulnerability in healthcare is more difficult, as there is less consensus on what the morally protected interests of patients comprise. When controversy exists about the existence of an interest, whether it is morally protected, or the degree to which it ought to be so, then we can at least require consistency. Recognising an interest as morally protected implies that we also recognise the patterns of vulnerability associated with it.

In the case of children, the fact that parents are expected to act as their child's protector adds a step to this analysis. Any circumstance that makes parents less likely to either act as protector or to be effective in protecting a child will compound the vulnerability of this child. In the case of children, fulfilling our duty to protect vulnerable persons must take this dimension into account. In some cases, the most effective protection may be indirect and aim either to improve the ability of parents to protect their children's interests or to provide children with an alternative primary protector.

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