

Exploitation, benefits and inducement



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Exploitation



- Claims about exploitation are frequent in the research setting
- Exploitation is often conflated with oppression, betrayal, coercion, assault, deception and discrimination, It is helpful to distinguish exploitation so that the right remedy can be applied to it
- Arises because of the difference in power, knowledge and authority between researchers and participants; between researchers and sponsors; between local and international researchers
- Exploitation is a moralized concept so one of the criterion for making a valid claim for exploitation is a moral one
- Moral weight of exploitation refers to the intensity of the wrongness

Moral weight of exploitation



- Exploitation manifests itself in micro-level transactions but some argue that it has its roots in macro-level injustice. That there would be less micro-level exploitation in a society that is just at the macro level
- Even if this were true, and it most probably is, we are not absolved of the need to look at the micro-level issues so that we can determine what must be done at this level and possibly at the macro-level in addition
- Exploitation may be *harmful* or *mutually advantageous*
- Exploitation may also be consensual (exploited has given proper informed consent) or non-consensual (as in the case of fraud or coercion)

Exploitation



- Typically in examining an action – there may be many moral issues at stake – and we tend to focus on the strongest moral wrong. For example, a murderer not only kills his victims but also unfairly uses them. In this situation, we would not focus so much on the exploitative nature of the act of murder, present though it is, but on the murder itself
- Similarly in reviewing research for exploitation, we should have excluded the greater harms of coercion, fraud and harm, where these are present. It is when these are absent that we consider those forms of exploitation that may occur within the context of research where often the transaction is potentially mutually advantageous or consensual

Exploitation



- This is generally defined as present when A takes unfair advantage of B. This can be understood in two ways
 - One way refers to some dimension of the *outcome* of the exploitative act or relation; and this too has two elements
 - The benefit to A
 - The effect on B
 - – wherein we may claim that it is wrong for A to benefit at all from his or her act on B or that his benefit is excessive relative to that of B within the context of the transaction
 - Secondly, we may imply that A has been able to turn some characteristic of B or some feature of B's situation to his or her advantage – a defect in the *process* of the transaction or agreement between A and B

Elements of Exploitation



- For the conditions to exist for A to take *unfair* advantage of B, the transaction must be such that A can take advantage of B, at all
- Harmful exploitation does not necessarily mean that B loses something (zero-sum – A gains and B loses). It may involve a negative-sum (A's gain is less than B's loss) or positive-sum (A gains by imposing a loss on B that is less than A's gain)
- Can A exploit B if B is not directly affected by A's utilization of B or if B gains from the transaction
- Consider cases of *harmless parasitism* – A uses B to his own advantage but B is not worse off

Elements of exploitation



- Consider situations where there is *heterogeneity of preferences* – where the elements of a transaction are valued differently by both parties and considered advantageous to both
- In considering whether there is harmful or mutually advantageous exploitation, we must take an all-things-considered view in relation to its net effect on B
- Mutually advantageous transaction is one in which B gains relative to the non-participation baseline even though the social surplus generated is unfair to B
- How does this relate to the Kantian interpretation of exploitation – where A merely uses B as a means to his own advantage rather than as an end in itself

Elements of exploitation



- How do we distinguish mutually advantageous transactions that are exploitative from those that are not
- Marxists and libertarians agree that there is a “force-inclusive” definition in exploitation
- We can see that force inclusiveness – coercion – need not be present for exploitation to occur
- Does consensual exploitation involve some sort of defect in consent that does not amount to coercion or fraud?
- Coercion compromises the voluntariness of consent
- Fraud compromises the rationality or advisability or validity of consent

Elements of exploitation



- There are cases of exploitation in which B's consent is not defective (by coercion or fraud)
- A may take advantage of B's circumstances to get B to agree to a mutually advantageous transaction to which B would not have agreed under better or perhaps more just background conditions, where A has no special obligation to repair those conditions and where B is fully informed as to the consequences of various choices. In this situation B may prefer that he has other range of options but he/she can still make rational decisions based on available options
- Even in such circumstance, we would still have to contrast the cases that are nonconsensual because of fraud or coercion and ask what the moral force amounts to

Moral force of exploitation



- Moral force refers to the various moral upshots or reasons for action that exploitation might or might not involve for parties to the transaction or for society
- Can people have a right to exploit?
- Is it wrong to allow oneself to be exploited?
- Should we refuse exploitative agreements
- The moral force of harmful and nonconsensual exploitation is straightforward
- It is, in such situations, wrong *prima facie*, to harm and the state is *prima facie* justified in prohibiting or refusing to enforce such transactions

In summary



- Exploitation is a micro-level concern. It is about harms arising from discrete interactions and not about the larger social and historical issues of injustice etc. These macro-level issues affect but do not replace the main issue
- Exploitation is about interactions – between the researcher and the participant or between the researchers and the community
- It is about “how much” and not about “what” each party receives. The key issue is fairness, not equal-ness of benefits
- The presence of vulnerability may make exploitation more likely but does not inherently entail exploitation

In summary



- Since exploitation is a micro-level concern, the key question is the level of benefits provided to the parties who interact. It does not involve weighing the benefits for those who do not participate in the interaction
- Determining when exploitation occurs requires interpretation since the concept of fairness depends on an idealized market condition
- Therefore reasonable people can and will disagree about what constitutes fair. This does not however invalidate the judgments made

Elements of exploitation



- In the Kantian view, one treats the other in a way to which he could not possibly consent – there is therefore an element of coercion or fraud. There is an element in which the autonomy of the individual as a decision maker is undermined
- Rawls looks at fairness at the macro-level – distribution of rights, liberties and resources for the basic structure of society with which individual transactions occur. It is not applicable at the micro-level

Elements of exploitation



- In considering exploitation, the ethics committee will be looking at the nature of the transaction between the researcher and the research participant
- What people are offered before they choose to participate. This is not related to their autonomy to consent
- It also refers to the concept of reasonable availability after the research is over

Benefits



- In therapeutic research – benefits may include relief from disease, diminished suffering or provision of diagnostic information
- In non-therapeutic research participants join for altruistic reasons to benefit society
- In exchange for these benefits, participants accept some risk. Acceptability of these risks reflect the participants goals and values. Payment may influence these calculations
- On the other hand, it may be argued that the financial reward is a benefit as valid as the other reasons – it should therefore be included in the risk benefit calculus. Excluding it may therefore violate individual autonomy to determine what monetary value, if any he places on participation in research

Benefits



- Another objection to payment of research participants is that it may entice economically disadvantaged persons and lead them to bear disproportionate amount of risk of research. This contravenes principles of justice
- On the other hand, it may be argued that measures that help to increase the participation of economically disadvantaged people in research is ethical. This assumes that research is beneficial
- This counter-argument is also not compelling from the utilitarian point of view. There may be no reason to believe that economically disadvantaged people as a group stand to benefit rather than benefit to only those who participate

Benefits



- Another argument against payment of participants is that this makes the participant a “salaried worker” and this changes the relationship between the participant and the researcher
- However payment for labor is not unethical and a person’s services or capacities are commodities that are regularly exchanged for wages
- Empirical data shows that payment is a primary motivator for participating in non-therapeutic trials
- In therapeutic trials, health improvement was the primary motivator to participate in research
- In developing countries, payment for lost wages, transport and other inconveniences make a strong justification for payment

Benefits



- Incentives may be necessary to recruit adequate numbers of research participants however there is limited evidence that this works any better than treatment or access to care
- Incentive helps to overcome opportunity costs, inertia, distrust and helps to recruit hard to reach participants
- Reimbursement for expenses and lost wages help to reduce the barrier of financial sacrifice for participants
- Payment represents fair compensation for time and inconvenience of participation
- Some argue that payment is a form of coercion. However coercion includes a threat of harm by definition therefore an offer of money cannot be called coercion

Benefits



- Payment may constitute undue inducement which may compromise informed consent by
 - Reducing interest in understanding risks related to research
 - Reducing the voluntary nature of the decision to participate
- Undue inducement is not well defined
- No evidence that money alters perception of risk
- Voluntary decisions can be made even when inducements are offered
- Other inducements may be as powerful or more powerful than money

Models of payment for the participation of research subjects

Model	Payment serves as	Amount determined by	Potential advantages	Potential disadvantages
Market	Incentive	Supply and demand; market rates	<ul style="list-style-type: none"> (a) More rapid recruitment. (b) Completion bonuses encourage subject retention and high completion rate. (c) Possibility of profit for participants. (d) Little or no financial sacrifice by subject. 	<ul style="list-style-type: none"> (a) Undue inducement possibly resulting in: incomplete assessment of risks and benefits by subject; subject concealing information to ensure enrollment/retention. (b) Competition between studies; better-funded studies more likely to meet recruitment goals. (c) Different levels of payment at different locations for multicenter trials.
Wage-payment	Compensation	Standardized "wage" for time and effort, suggested to be commensurate with wages for unskilled, but essential jobs; additional payment for extra burdens such as endurance of uncomfortable procedures	<ul style="list-style-type: none"> (a) Recognizes contributions of participants. (b) Uniform payment across studies. (c) Equal pay for equal work. (d) Less risk of undue inducement. 	<ul style="list-style-type: none"> (a) May have little impact on recruitment. (b) Might undercompensate some subjects in relation to regular wage and preferentially attract others.
Reimbursement	Reimbursement	Expenses incurred (transport, meals, lodging); with or without reimbursement for lost wages	<ul style="list-style-type: none"> (a) Makes research participation revenue neutral. (b) Little risk of undue inducement. (c) Little or no financial sacrifice for subject if lost wages are reimbursed. 	<ul style="list-style-type: none"> (a) May have little impact on recruitment. (b) Uneven reimbursement from subject to subject. (c) Reimbursement costs for high-salaried subjects may result in the targeting of low-income populations. (d) Financial sacrifice for subject if lost wages are not reimbursed.
Appreciation	Reward	Token of appreciation given at the conclusion of study	<ul style="list-style-type: none"> (a) Expresses gratitude for contribution made. (b) Not market dependent. (c) Avoids undue inducement. 	<ul style="list-style-type: none"> (a) Likely to have no impact on recruitment. (b) No basis for consistency.

Benefits



- Another model for payment is the fair-share model which views the participant as a partner in the drug development process
- Payment is based on a percentage of the per-patient compensation due the investigator or the institution
- Payment would be for completed components of the research only
- The criticisms of this model include that payment is based on a per payment compensation rather than on level of risk borne by participants; not all research is about drug development; too much variation; competition would favor studies with more funding

Benefits



- Some differentiate between paying healthy participants and paying patient-participants
- Healthy participants are often motivated to participate in research by money and receive little or no other benefits from participation whereas commentators worry about the vulnerability of patient participants
- Illnesses make people vulnerable in many ways
- In fact offering money may help participants more clearly distinguish research from treatment and reduce the risk of therapeutic misconception
- This may also empower the participant to say no to participation without feeling obligated

Inducement



- Inducements are pervasive in life.
- Exchange of goods for the purpose of alteration of behavior occurs without raising concern
- In fact such inducements may make people take on more risky occupations
- So when is inducement *undue*?
- CIOMS “Payment in money or in kind to research subjects should not be so large as to persuade them to take undue risks or volunteer against their better judgment. Payments or rewards that undermine a person’s capacity to exercise free choice invalidate consent

Inducement



- Undue inducement requires 4 conditions
 - An offered good - Individuals are offered something that is valuable or desirable in order to do something
 - Excessive offer – The offer must be so large or in excess that it is irresistible in the context
 - Poor judgment – The offer leads individuals to exercise poor judgment in an important decision
 - Risk of serious harm – the individuals’ poor judgment leads to sufficiently high chance that they will experience a harm that seriously contravenes his or her interests

Inducement



- Compared with coercion
 - Undue inducement dangles a positive good before the participant – a tempting offer that can cause to bad judgment and lead harm
 - Coercion entails a threat that the person considers a worse circumstances if they do not do the desired action
- Compared with exploitation
 - Exploitation involves a person getting too little while undue inducement entails a person receiving too much

Inducement



- Differentiating undue inducement from unfortunate circumstances
 - Distressing circumstances that create limited options do not necessarily compromise autonomy and voluntariness
 - Tempting offers in desperate situations that have clear good results are not undue inducements
 - Irresistible offers become undue inducement when a person's unfortunate circumstances and compromised judgments are combined with accepting a seriously unfavorable risk-benefit ratio that threatens fundamental interests

Compensation for research injuries



- Participants in research may suffer injury because
 - Research procedure – e.g. falling off the treadmill and fracturing a bone; headaches after a spinal tap
 - Injuries may result from the medication or device being tested
 - From failure of the investigator to follow the protocol
 - Failure of the investigator to perform research associated procedure properly
- Occurrence of serious injury is rare in clinical trials/research

Compensation for research injuries



- International guidelines on provision of compensation for research associated injuries vary widely
- Some suggest that sponsors and institutions are obligated to compensate injured participants, particularly when there is a commercial sponsor, regardless of who is to blame or whether participants were paid
- Another view is that participants were aware of the risks through the informed consent process and voluntarily agreed to participate
- There are also practical issues
 - It may be difficult to determine whether the medical problem is related to research participation
 - Particularly if it develops months or even years after the research

Compensation for research injuries



- The cost of providing compensation includes the need to adjudicate claims and resolve disagreements
- Plans with broad coverage are more costly and difficult to administer than those limited to direct costs only
- Research participants need to be told whether compensation or medical treatments are available for injuries, if so, what they are and where they can obtain further information about them

Compensation for research injuries



- In the U.S., sponsors and institutions are not required to provide either free medical care or compensation
- In many European countries on the other hand, clinical trials insurance is mandated through which participants are covered regardless of fault
- In Nigeria, researchers conducting clinical trials are enjoined to obtain insurance in case of research injury