Exploitation, Benefits, Inducement and Compensation for research participants

Ayodele S. Jegede

Outline

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Objective

- To build participants capacity to be able to determine measure of benefits, inducement and compensation appropriate for research

Message

- Fairness to research participants is determined by appropriateness of benefits, inducement and compensation for research injuries
Exploitation?

- Exploitation frequently reported in research setting

- Often conflated with oppression, betrayal, coercion, assault, deception and discrimination

- Power relation issues: Arises because of the difference in power, knowledge and authority between researchers and participants; between researchers and sponsors; between local and international collaborators

- Moral weight of exploitation is about 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

- 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)
Elements of exploitation

- **Heterogeneity of preferences** – where the elements of a transaction are valued differently by both parties and considered advantageous to both.

- **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.

Elements of exploitation

- Distinction between mutually advantageous transactions that are exploitative and 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

- In 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.

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 equality of benefits.

- The presence of vulnerability may make exploitation more likely but does not inherently entail exploitation.
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 risks.

- 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/she 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

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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.
What is inducement?

- Inducement, in the context of research, is a reward given to anyone who volunteer to participate in a research.

- The examples of inducement are free care, medical examination, provision of drugs, gifts, and cash. Payment of cash appears to be the most common type of inducement (Dicket et al, 2002).

Reimbursement

Research participants may be reimbursed for:

- Transport expenses for participants who have to travel to get to research sites

CIOMS on Inducement

- “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

- Is inducement necessary in research? If yes, why?
Why is inducement necessary?

- Some inducement is necessary to prompt sufficient number of persons to enroll in research (Dicket et al., 2002; Macklin, 1981); payment is made to enroll and retain participants in a study.

- Participation in a research is an opportunity cost (people forgo some activities in order to participate in research) so inducement is a form of payment for lost time, and earnings.

- Participation in research may be inconvenient (e.g. staying in a hospital, answering personal and sensitive questions).

- Participation in a research involves risks (physical, psychological, emotional) and benefits; but some participants do not directly benefit from a research but bear the risks and therefore paid for this purpose.

- When does inducement becomes a problem?

Features of Undue 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 their interests.
Inducement vs Coercion and Exploitation

- **Undue inducement is sometimes 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
Undue inducement: the counter argument

- Undue inducement is often 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
- Sometimes confused with coercion. However coercion includes a threat of harm by definition therefore an offer of money cannot be called coercion

Challenges of inducement [1]

- The main ethical concern with inducement is that payment should not be so large, or medical services so extensive as to induce prospective subjects to consent to participate against their better judgment (undue inducement) (CIOMS, 2002)
- Any payment or reward that is so large as to undermine a person's capacity to exercise free choice has invalidated consent
- Another potential source of undue inducement is in raising excessive or unrealistic enthusiasm about the possible benefits of the research to potential participants;
- e.g. promising prospective participants that a drug being tried will cure a health condition (Dunn and Chadwick, 2002)
- At the same time payment should not be too low as to serve as an exploitation of research participants
Challenges of Inducement [2]

- It is sometimes difficult to distinguish between acceptable inducement and undue influence to participate in research in some settings.

- For example, an unemployed person or student may view payment differently from an employed person.

- Someone without access to care may or may not be unduly influenced to participate in research simply to receive such care.

- For example, in the trial of the drug Trovan by Pfizer, any patient who wanted good quality care must enroll in the study because the best available bed space was offered to anyone willing to participate.

- A prospective research participant may be induced to enroll in research to obtain a better diagnosis or access to a drug not otherwise available (CIOMS, 2002).

Problems with inducement in Poor Research setting [1]

- The distinction between ethically acceptable monetary inducement and undue inducement of research participants is blurred in Nigeria because of widespread poverty.

  - For example, the percentage of Nigerians living in absolute poverty rose from 28% at independence in 1960 to 48% in 1998 (UNDP, 2001). Poor persons may enroll in a research that is not in their best interest if there is a prospect of receiving of inducement.

- There is no written policy in many institutions in Nigeria regarding payment of research participants; so each researcher uses his own judgment in fixing the amount of money to be paid to research participants.
Problems with inducement in Poor Research setting [2]

- Monetary inducement of research participants is also contentious because of precedent setting.

- Because budgets available to conduct research are not always equal and because risk involved in studies varies, payment of a uniform amount of money to research participants in all research is not realistic.

- Externally funded reproductive health research projects typically have higher budget profile than those funded by the researchers themselves.

- Participants who have benefited from a generous monetary inducement from a buoyant budget will expect and even demand the same or better inducement when other researchers with limited budget invite them to participate in a research.

Problems with inducement in Poor Research setting [3]

- This may undermine the scientific integrity of the research by altering the composition of participants enrolled for the study (Dickel et al, 2002).

- Yet, research participants need to be adequately compensated for the inconvenience they suffer and the risks they bear in taking part in the research.

- One way of minimizing the role of financial inducement in undue influence is to fix payment based on minimum wage.

- However, this approach creates its own tension in that it may undermine the principle of justice which requires that the burden and benefits of participation in research should be fairly distributed among all segments of the society.

- Ruth Macklin has pointed out, setting payment as would be necessary to gain research participants would virtually ensure that those participants are drawn from people of lower social and economic classes (Macklin, 1981).
Problems with inducement in Poor Research setting [4]

- The challenge therefore is in finding an amount of money adequate enough to compensate research participants for their efforts and small enough to attract a broad spectrum of research participants.

- One way of addressing this problem may be to offer research participants in-kind payment instead of money.

- Although the materials offered also have financial value, it may have diminished role of inducement if this is not disclosed during recruitment process.

- Many research projects in Nigeria are increasingly adopting this strategy of offering research participants condoms and educational materials such as posters and handbills on HIV prevention as an alternative to monetary payment.

Key point

- Payments in money or in kind to research participants 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 (CIOMS, 2002)
How to make inducement ethical

- A guardian asked to give permission on behalf of an incompetent person should not be offered any recompense other than reimbursement for travel cost.

- A participant who withdraws from a study due to adverse events such as side-effects of the study drug, or withdraws on health grounds should be paid as if full participation has taken place.

- A participant who withdraws for other reasons should be paid on a prorated basis: prorated payment recognizes the actual time and effort a participant contributes to the research and is less likely to pressure the participant into completing the study or concealing information in order to receive money (Dicket et al, 2002).

- An investigator who must remove a participant from a study for willful noncompliance is entitled to withhold part or all of the payment (CIOMS, 2002).

Compensation for research injuries [1]

- 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 [2]

- 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 [3]

- 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 [4]

- 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

Compensation for research-related injuries

1. Where appropriate, as determined by HREC, researchers and research sponsors shall provide complete medical care and commensurate compensation for all research related injuries that participant may suffer

2. Where appropriate, as determined by HREC, researchers and research sponsors may be required to provide evidence of insurance coverage of the research to provide adequate compensation for research related injuries, their care and compensation

3. Under no circumstances may research participants be asked to waive their legal rights, including the right to legal redress of research related injuries and compensations
Free treatment/referral

- When prospective research participants are found to have unrelated disease to the research or cannot be enrolled in a research because they do not meet inclusion criteria, investigators should as appropriate provide free treatment or refer such persons to an appropriate agency for care.

Role of HREC

- All payments, reimbursements and medical services provided to research participants must be approved by the HREC.

- Monetary and in-kind payment must be evaluated in the context of the traditions of the particular culture and population in which they are offered, to determine whether they constitute undue influence.
Acknowledgement

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THANK YOU ALL