

ETHICS IN HEALTH CARE: INDUCEMENT AND HUMAN SUBJECTS

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Abstract: Currently, most health researchers or donor organizations consider inducement as a vital part in promoting research. They propose benefits, such as post research free medical treatment, food, insurance facilities, or even cash, in order to meet sufficient number of subjects. So, inducement may influence one to participate in a research. Is it ethical to offer inducement to human subjects? What are the risks in such practice? What will happen if the donor agencies use subjects by hiding possible risks from them? When an inducement can satisfy ethical criteria? The CIOMS, FDA, and other ethical guidelines hold that inducement is unethical because it involves enough risk for voluntary informed consent. Supporting this position, a group of ethicists has argued that inducement undermines voluntariness especially when subjects are poor and vulnerable, and thus, unethical. In contrast to them, others argue that inducement contributes to discover new knowledge which can improve miserable condition of the poor. In their view, an inducement maintains all ethical criteria including subject's autonomy, and therefore, morally permissible. The paper focuses this debate and analyzes both types of argument. It examines whether inducement invalidate informed consent. Even if inducement may not violate the basic components of informed consent, the paper concludes, subjects may claim a *prima facie* right to enjoy research outcomes.

Keywords: benefits, ethical guidelines, inducement, informed consent, risks, subjects, *prima facie* right.

INTRODUCTION

There might have several reasons to offering inducement in research. Inducement seems necessary to get sufficient subjects, to compensate for subject's time, for their welfare, or simply to co-operate in overcoming serious health problems. Not only money but also treatment, free medicine, and health care services for certain time may

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also be regarded an inducement. Now, is it ethical to offer inducement in clinical research? What is the demarcation line between due or undue inducement?

By quoting the CIOMS Guideline 7 some ethicists argue that inducement is unethical because it invalidates informed consent. Especially, when subjects are vulnerable or dependent inducement may strongly influence their consents. According to them, inducement is not only unethical but also harmful because by definition research aims to know what is unknown and the result or risk of research is also unknown. So, it is unethical to use people in risky jobs by providing few material benefits. By contrast, other ethicists claim that inducement does not invalidate informed consent requirement. As voluntary participants are ethically allowed with no payment there is nothing wrong, according to them, to pay someone for conveyance and time spent. Moreover, it might be difficult to get always voluntary participants, and inducement is *not* the only determinant for moral acceptability of a research.

In addition to this, moral acceptability of a research depends on the whole procedure or methodology of research. Taking permission from Research Ethics Committee is one of these procedures. The ethics committee has the responsibility to monitor research activities. They will not permit highly risky research that exploit people. So, inducement has no negative impact on better judgment, but rather it will help to make better judgment. Clearly, there are arguments for and contra inducement. I will analyze both types of argument after discussing what inducement is and what relationship exists between inducement and informed consent. I will then argue that inducement is ethically acceptable so far it will not be used as a means to obtain informed consent. Inducement is justified because subject has *a prima facie* right to enjoy research outcomes.

WHAT IS INDUCEMENT?

When a researcher or donor organization offers money or some sort of benefits for research subjects that added value can be defined as inducement. Inducement is widely used as a synonym of salary, wage, incentive, bonus, free health care facility, free medicine and even food. Some ethicists, such as Wilkinson and Moore, even think that inducement could be a 'reward' since both parties are gaining something 'mutually' in this process. They write, "As a result of

offering the reward, the researchers get the subjects they want. As a result of participating, the subjects get the reward they want. Both are better off. No one is worse off¹.

However, there are some difficulties to consider inducement as reward or wage. Since reward is given an individual to motivate for better performance in future by acknowledging his or her present achievements. Reward has a motivational function. In a similar way, wage is strongly related with right. Wage earners may enjoy overtime payment, fixed working hours, etc. They also have a responsibility toward the company or the organization for their contractual relationship to it².

So, inducement has a different meaning in common usages. Generally, it is an offer or an opportunity. Although inducement is an offer intending some mutual benefit it has a moral significance. In the moral sense, inducement could be due or undue. The *amount* or the *quantity* of inducement is the key factor to demarcate between 'due' or 'undue'. Inducement may be considered as compensation or welfare. Some noticeable features of inducement are: firstly, inducement is offered in order to get sufficient subject. Secondly, inducement refers some kind of benefits for the subject as well as the researcher. Thirdly, inducement is acceptable in so far as it does not change subject's behavior very rapidly. Fourthly, inducement is closer to compensation rather than wage or reward. Finally, inducement is compatible with welfare.

INDUCEMENT AND INFORMED CONSENT

Informed consent is an important requirement for any clinical research to be considered as ethical. Since it is not morally acceptable to act against subject's wishes and ignore her dignity, informed consent may be defined her formal or oral voluntary approval to participate in a research. Researchers have an obligation to protect subject's autonomy and respect human's dignity. The CIOMS Guidelines relate inducement and informed consent by defining informed consent as "a decision to participate in research made by a competent individual who has received the necessary information; has adequately understood the

¹ M.Wilkinson, A.Moore (1997). *Inducement in Research*. "Bioethics" 11 (5), pp. 375-376.

² R.W.Grant, J.Sugerman (2004). *Ethics in Human Subjects Research: Do Incentives Matter?* "Journal of Medicine and Philosophy" 29 (6), pp. 719-720.

information; and after considering the information, has arrived at a decision without having been subjected to coercion, undue influence, inducement or intimidation (Commentary on CIOMS Guideline 4)”³.

This guideline suggests that informed consent has to be obtained without inducement or coercive offer. However, all inducements may not be ethically problematic because inducements are very common in our every day lives and we morally permit them. Emanuel mentions, “Indeed, inducements are so commonplace and acceptable that our daily lives would be drastically different if they were all prohibited as unethical”⁴.

But when is inducement ethically unacceptable? Inducement which dramatically influence people’s judgment or consent, inspire them to participate some harmful jobs may be called ‘undue inducement’ i.e. unethical inducement. Emanuel, Currie and Herman identify four ‘aspects of undue inducement’: “1.an offered good-individuals are offered something that is valuable or desirable in order to do something. 2.excessive offer-the offered good must be so large in excess that it is irresistible in the context. 3.poor judgment-the offer leads individuals to exercise poor judgment in an important decision. 4.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.”⁵

According to them, any undue inducement must contain these four aspects. Despite harm another important issue related to inducement is ‘coercion’. Coercion refers ‘threat’ or ‘pressure’ to participate research. Wilkinson and Moore state, “Coercion is paradigmatically a case of the denial of autonomy, since it consists in the deliberate imposition of one person’s will on another” (1997, 378). So, coercion necessarily involves a physical or mental harm of the subject. It happens when subject participates forcefully in research against her will.

But can inducement be coercive? There is no specific answer to this question as inducement refers to some benefit while coercion refers threat or harm. Grady says that “...since the offer of money is not

³ P.Andanda (2005). *Module Two: Informed Consent*. “Developing World Bioethics”, Volume 5 Number 1, p.16

⁴ E.J. Emanuel (2004). *Ending Concerns About Undue Inducement*. “Journal of Law, Medicine & Ethics” 32, p.100.

⁵ E. Emanuel, X.E.Currie, A.Herman, A. (2005). *Undue inducement in clinical research in developing countries: is it a worry?* “Lancet”, p.336.

a threat of punishment or harm, but rather an offer, it is hard to see how money as payment for research participation is or could be coercive”⁶. However, some ethicists disagree with him. Emanuel, Currie and Herman give the example of coercion as “Your money or your life” (2005, 336).

From this discussion, it is clear that inducement and informed consent are intimately connected. Undue inducement and coercive offer are ethically unacceptable since both of them may invalidate informed consent. In undue inducement, subject is encouraged to getting something desperately, while in coercion, she is threatened by physical or mental harm. But can inducement invalidate informed consent even if it is neither undue nor coercive? We will review this question in the next section.

ARGUMENTS CONTRA INDUCEMENT

Almost all ethical Guidelines and Codes discourage inducement. One of the main reasons of discouragement is that inducement invalidates informed consent. The Council for International Organizations of Medical Sciences says in Guideline 7, “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” (Emanuel, Currie and Herman 2005, 336).

National Health and Medical Research Council of Australia states, “Volunteers may be paid for inconvenience and time spent, but such payment should not be so large as to be an inducement to participate” (Wilkinson and Moore 1997, 373). So, these Guidelines emphasize that inducement may ethically be questionable.

Three arguments are presented in supporting of these Guidelines. The first argument for invalidate informed consent is that subject may not consider the risk because of getting benefit and gives her consent which is not ethical. Ballantyne puts forward this argument in this way, “The paternalistic argument against inducements is that...potential participants would be ‘blinded’ by the offer of money

⁶ C. Grady (2001). *Money for Research Participation: Does It Jeopardize Informed Consent*. “The American Journal of Bioethics” 1(2), p.41.

and might, therefore, undermine the risks of research, overestimate the benefit of the cash payment or adequately weight the risks”⁷.

Risk is an obvious part of research. Some clinical trials are high risky and may have extreme side effects. For example, Resnik writes, “...they often are time-consuming, uncomfortable, and painful. Subjects may stay in a medical facility for several days, they may be given a variety of medical test...and they may experience various toxic effects...it is likely that most volunteers agree to participate in order to make money.”⁸

In this argument, at least we should recognize that there are some risky research trials which are uncomfortable and time consuming. But, is that claim justified that people participate voluntarily in research only for benefit? Are they influenced by inducement and then give their consent? Both of the answers of these questions could be ‘No’ because there are many risky jobs in our society and there we participate willingly. We are not able to predict all the risks involving in our daily lives. For example, we go to university by bike or by walk through busy and risky highways without knowing when the accident will occur. Take another example given by Resnik: “In eastern North Carolina thousands of migrant workers prime, pick, and bundle tobacco every summer when the heat index is well over 100 degree F. This is a job that is arguably much more dangerous, uncomfortable and painful than participating in research.” (Resnik 2001, 55)

Imagine that these workers are not to be paid for their labor. Will it be better? It seems to me ‘No’ because it will not improve the scenario. Rather they will be happy if they were paid a fair wage.

The second argument is about better judgment. When inducement is offered it undermines the subject’s better judgment. Prior to participate any research a subject should think back and forth, e.g. what might be the justifications for her participation. But if subjects were offered inducement, they might participate to get the benefit and don’t consider other factors to make their judgment better. Resnik sates this argument as, “Some writers have argued that we should take steps to protect healthy, poor volunteers from agreeing to

⁷ A.Ballantyne (2006). *Benefits to Research Subjects in International Trials: Do they Reduce Exploitation or Increase Undue Inducement?* “Developing World Bioethics” doi:10.1111/J.1471-8847.2006.00175.x, p.7

⁸ D.B.Resnik (2001). *Research Participation and Financial Inducements*. “The American Journal of Bioethics” 1 (2), pp.54-55.

participate in research, because they are economically vulnerable and may act against their better judgment” (Ibid, 55).

This argument also has some limitations. It is possible to argue that making such type of claim will devalue rationality of human beings and creates mistrust about people’s judgments. Since if we accept that the research subject is competent and able to participate then we cannot question their judgment. For example, let us assume that a research organization is conducting research on drug addiction and some university students participate that trial as subjects. We could imagine that these students at least have some ideas about drugs or they have been provided enough information about drugs and their affect. Now, can we say that their judgment is not a better judgment? There might be many causes to participate in this research trial to these students, inducement is one of them.

Resnik himself disagrees with this ‘better judgment’ argument. He says this argument is ‘overprotective’. That is, this argument tries to protect people from making their judgments. As a competent person we take good as well as bad decisions. We make judgments based on our rationality, competency, autonomy, and liberty. Although it may not possible to make always better judgments our freedom to make bad decisions or bad judgments should be respected equally. His second reply is that this argument ‘overestimates the degree’ at which level inducement can influence a competent person’s judgment. He says, any one has the right to refuse to participate in research. No subject is bound to participate. Inducement may influence our decision but certainly it will not force us to make a bad judgment (Ibid, 55).

The third and final argument for invalidate informed consent is about vulnerable people especially the poor people. It says that vulnerable people (e.g. poor, illiterate, dependent, prisoners, etc.) might have only option and that is to participate in research for money or some other benefits. Even they might not be able to understand what informed consent is. So, offering inducement to them is unethical. Emanuel, Currie and Herman put forward this argument as, “Many worry that poverty or otherwise compromised circumstances may force people to take an inducement... offers are said to undermine autonomy and voluntariness and therefore, informed consent” (2005, 338).

It is an important issue that if subjects are poor then there is a chance to be exploited. They will be very much eager to get benefit from the researchers anyway. As a result, researcher could take an opportunity to conduct risky trial on them. Another point is that it

might be easy to get the poor as subject by paying unfair inducement. McNeill very strongly argues against inducement from 'equity' perspective. He says, "It is not equitable that the poor are encouraged to expose themselves to risks of harm, by the offer of a financial inducement, especially when the potential benefit is to others"⁹.

However, there is no good reason to accept this argument against inducement. Because even if the subjects are poor and vulnerable it does not imply that they will be unable to make autonomous decision. They are competent person and agree to participate willingly. Inducement will not decrease their moral status as a human being. Moreover, 'equity' or 'equality' is a very difficult term to be defined. From the very ancient time philosophers (e.g. Plato, Rawls, etc.) and economists (e.g. Adam Smith, Marx) have been tried to define it. Wilkinson and Moore reject this 'equity' argument accordingly. They claim, "The equity argument against inducements is the vaguest that we consider. This is partly because, without a great deal of clarifying explanation, the idea of equity is itself vague...here are some of the things that would have to be shown before the equity objection even *applies* to our position, let alone outweighs the positive reasons for permitting inducements."¹⁰

From the above discussion, I have tried to show that arguments which claim inducement invalidates informed consent are not fully sound. All three arguments explain some factual events (e.g. risk, economic status, etc.) and then made a normative conclusion which is unsatisfactory.

ARGUMENTS FOR INDUCEMENT

Some scholars have claimed that inducement does not invalidate the informed consent requirement. Rather they argue for reasonable or acceptable level of inducement to the subject. They reject the 'orthodox argument' which says that inducement is against research ethics. Although these authors argue for inducement they agreed that undue inducement and coercion are ethically unacceptable. In this section, I will analyze two important arguments offered by them.

⁹ P. McNeill (1997). *Paying People to Participate in Research: Why Not?* "Bioethics" 11 (5), p. 395.

¹⁰ M. Wilkinson, A. Moore (1999). *Inducement Revisited*. "Bioethics" 13 (2), p. 116.

Firstly, in our daily life leading we use inducements very often. Sometimes we offer inducement to our subordinates or we receive inducement as a subordinate from the prime person. We do it mutually and voluntarily. It does not invalidate our informed consent requirement. This type of transaction is not harmful for each other rather than beneficial. Everybody is happy. Wilkinson and Moore mention this situation as ‘mutual better off’. McNeill gives an example to clarify their argument. He says let us assume that Mr. X is working as a receptionist of a doctor. The doctor pays him for the extra time he spent. Both the doctor and the receptionist are happy because they are free to take decision and equally benefited (1997, 391). Wilkinson and Moore state, “People receive inducement all the time.... There is no suggestion in the vast majority of these cases that their being paid undermines the voluntary nature of their actions” (1997, 376). So, as we ethically accept these types of inducement in every sphere of our lives there is no reason to say that inducement in research is unethical.

However, I disagree with this analogy. Because in this example the relationship between the doctor and the receptionist is contractual and contractual relation is only possible when both parties agree that they will *not* break or refuse the contract. In researcher-subject relationship subject *has* the full right to refuse his or her participation at any time. McNeill also disagrees with this analogy. He clearly writes, “I simply disagree on the ground that two are not equivalent and that work is not an appropriate analogy for participating in research” (McNeill 1997, 391).

McNeill disagrees for two reasons. First, since serving as a receptionist and as a research subject are two different types of job. Secondly, the necessities of the risky work to society. Society needs firemen for the greater benefit of people. Although it is risky someone has to do this job. It does not justify that someone must have to participate in risky research. Many risky and dangerous works are still prohibited in society. Research has some potential benefit. But participate in risky research is not necessary to society as the service of firemen (Ibid, 391-392).

The second argument contra invalidate informed consent is that informed consent protects autonomy *not* freedom. Wilkinson and Moore gave an example to explain this argument. Suppose if a person has the only alternative to take some life saving treatment than death then he or she is unfree to choose other alternatives. However, he or she is still autonomous to accept or refuse the treatment. All the

necessary conditions for taking autonomous decision are present here (1997, 377). By this analogy they tried to show that even the subject is in ‘desperate need’ inducement does not undermine their autonomy. So, alternative choice is related to freedom than informed consent and informed consent protects subject’s autonomy not their freedom. In their words, “...consent protects autonomy rather than freedom” (Ibid, 378).

To them, ‘autonomy’ and ‘freedom’ are different conceptions. Freedom means if we have two or three options then we are free to choose any one of them. By contrast, autonomy is the capability of a person to make decision. For example, we have freedom either participate or do not participate in a research. We will be autonomous if no one imposed his or her will on us which option we should choose. Informed consent protects autonomy to ensure that subject has participated without pressure and she has the capability to make her own decision.

SHOULD INDUCEMENT BE UNACCEPTABLE?

Informed consent is a core requirement in research ethics. The aim of informed consent requirement is to ensure that the subject has given her consent voluntarily i.e. there was no pressure or influence to make her decision. Indeed, informed consent itself has some limitations especially when the subject is poor, illiterate and dependent.

Now, why not inducement invalidates informed consent? I will make an analogy to answer this question. Let us assume that a university professor conducted a research on gene therapy. Some students in her university voluntarily participated in that research. She published her research findings which were considered the most fundamental contribution to gene therapy. As a result, she is nominated to receive the Noble Prize in medicine. Do the students have any right on this Noble Prize? I think that surely they don’t have right on Prize money but they have a *prima facie* right than other people in the world to be benefited from the research findings.

When subjects voluntarily participate in a research it implies that their intension is to benefit humanity. Four basic elements of informed consent are: “a.Capacity to consent. b.Full disclosure of relevant information. c.Adequate comprehension of the information by the participant. d.Voluntary decision to participate and withdraw from

participation at any stage without prejudice to the participant.” (Andanda 2005, 17)

None of these elements will be violated if inducement is being offered. Rather participation with inducement could justify the *prima facie* right. Subjects could claim to be benefited from the research in any time. For example, if they voluntarily participate in an AIDS research then they should have a priority or greater access (i.e. a *prima facie* right) to get medicine when it will be invented. However, the success of any research is uncertain, and even after success there is a market mechanism, which also need to consider. For this reason the best possible option for researcher is to offer instant benefit in any manner. A subject has the full autonomy to accept or refuse offer and that is why inducement may not invalidate informed consent.

CONCLUSION

Although some research is risky and people may influence to participate in those research for inducement it is not obvious. To protect such type of activities International Organizations have developed research ethics in which informed consent is one of the core requirements. Inducement not necessarily invalidates informed consent. Inducement in research should be allowed only when it is ethical, neither undue nor coercive.

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