

Incentives in human subject research



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The use of incentives permeates throughout all aspects of medicine; from bonuses for holiday or overnight shifts, to loan forgiveness programs for physicians practicing in underserved areas, incentives serve an important role in promoting patient care. In the vast majority of situations, the use of incentives in medicine is an unproblematic and elegant solution to issues with staffing or access to care. However, when employed in human subjects research (HSR), the use of incentives is often uncharted territory[REM1].

There are limited formal guidelines that delineate the correct application of incentives and compensation in research, and the issue remains largely unresolved. Thus, the ethics[REM2] of compensation often boils down to the specific type of patient population under study. In this paper, I will discuss the differences between vulnerable and non-vulnerable patient populations, and expound on the use of incentives in each of these populations in the context of modern medical ethical codes.

Definitions

As stated previously, the use of incentives in most aspects of medicine is rarely considered unethical. It is only when incentives – monetary or otherwise – are used as undue[REM3] influence in order to promote participation in a study that the use of incentives can cross an ethical boundary. Oxford English Dictionary defines undue influence as “ influence by which a person is induced to act otherwise than by their own free will or without adequate attention to the consequences.”[1] Therefore, one of the most important concepts in a discussion about the ethics of incentives in human subjects research is that of a vulnerable subject, because it is this

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population of patients that is most sensitive to the “undue influence” of incentives. We learned in Dr. Looney’s lecture “Research with Vulnerable Subjects” that there are several categories that define this population. In general, a vulnerable subject would be anyone that has limitations on either their mental capacity or their voluntariness to participate in research; it is this latter definition that is most sensitive to undue influence. Thus, some examples of vulnerable subjects include people in emergency situations, children/infants/embryo, the mentally ill, people of a low socioeconomic or educational status, people with terminal illness, and people in hierarchical organizations where there are power differentials. While this list is by no means exhaustive, it gives an important sampling of patients that are often recruited by researchers, and who might be especially susceptible to undue influence by means of compensation in order to participate in a study[REM4].

Ethical Codes

In order to properly discuss the ethics of incentives in HSR, it is imperative to also determine a set of ethical codes by which the issue of incentives can be judged. One of the most well known frameworks for medical ethics was the Belmont Report, drafted in 1979.[2] While there exist many other criteria for ethical research, such as the 7 Requirements posed by Emanuel et al[3], the Belmont Report is still considered to be one of the most widely known and widely cited works of ethical research involving human subjects. In the Report, there are three key ethical principles pertaining to human research: those of beneficence, respect for persons, and justice. Briefly, beneficence is the ethical duty to provide some sort of benefit to research subjects; in other words, this concept implies that the research in question minimizes risks and

maximizes potential benefits to participants. Next, respect for persons is closely related to the principle of autonomy, and implies the right of the subject to be left alone[REM5]. Thus, the principle of ‘ respect for persons’ is crucial when considering the voluntariness of an individual to consent to or refrain from participating in a study. Lastly, the principle of justice refers to the right of the individual and populations to be selected fairly for research, allowing all populations equal access to the benefits of research as well as ensuring that vulnerable populations are not being unfairly targeted. In presenting arguments about the ethics of human subjects research, we will therefore use the 3 main ethical principles of the Belmont Report to examine incentives for both vulnerable and non-vulnerable populations.

Incentives in Non-Vulnerable Populations

With respect to incentives in a hypothetical non-vulnerable population, we will examine whether there are any conflicts with the aforementioned ethical codes. Of course, the definition of a non-vulnerable population is a subjective one, as most human interactions have some level of a power differential between the participants; thus there are very few situations in research where a subject is completely non-vulnerable and not subject to some form of a power dichotomy[REM6]

When considering the principle of beneficence, there is little violation of this code with regards to incentives in human subjects research, if the research has been deemed to have a reasonable risk: benefit ratio. With a non-vulnerable and competent consenting subject participating in research that

has been IRB-approved and appropriate, there is no real ethical quandary between incentives and beneficence[REM7].

Next, we consider respect for persons, or autonomy. In a population where power-differentials have been minimized, the patients should have no effect on their free will to choose whether or not to participate in a study[REM8]. Thus, a fair and appropriate incentive would not make them go against their own best judgment to participate in the study, since this latter point would be considered a form of coercion or undue influence. For example, I propose this hypothetical situation: if there were a study that required a number of blood draws and the incentives in this case were monetary, then targeting a population that is financially stable would likely not significantly affect their autonomy; they should be able to weigh the risk and benefits and decide to participate based purely on their own best judgment. However, this situation might be very different when primarily targeting a low income population, where the subjects might have major qualms about needles or getting their blood drawn, but would feel forced[REM9] to agree to participate due to their need for financial resources.

Finally, we consider the juxtaposition of the ethical principle of justice and incentives in non-vulnerable populations. Once again, as with the beneficence, there are really no ethical quandaries in this situation, as there should be fair and equal subject selection with no large variations in access to research. It is only when dealing with vulnerable or “difficult to reach” populations (i. e., underserved minorities, prisoners, children, people of low socioeconomic status) that there might be issues with the concepts of justice and compensation. Thus, it is clear that when considering non-vulnerable

populations, there are no real issues with using incentives to promote participation in approved human subjects research[REM10]. The real ethical quandaries arise when there are major differences in power, status, or ability to make autonomous decisions.

Incentives in Vulnerable Populations

We will now revisit our familiar ethical codes and discuss them in a different light, focusing on vulnerable populations and using specific historical examples when applicable. In the case of beneficence, it is mostly the job of the research team and governing boards to minimize risk and maximize benefit; thus the use of incentives does not really enter into play here. The only situation in which incentives might alter the researcher's concept of beneficence, is if, for example, there was a study with a high risk and variable benefit, but the compensation was also comparably large; in this situation, the research team could therefore argue that it is up to the participants to decide the level of risk they are willing to take in exchange for again[REM11].

Respect for persons goes hand in hand with autonomy and voluntariness, and it is possibly the most difficult ethical principle to reconcile with incentives in vulnerable populations. In class, there are a few scenarios where incentives to vulnerable populations have resulted in abuse of certain research participants. For example, there was the instance of the US Public Health Service Guatemala STD study, where prisoners (a vulnerable population) were incentivized with prostitutes to participate in a study assessing syphilis and gonorrhea transmission; while this study also had

major problems with the informed consent process, it also brings to light the issue that in certain populations such as prisoners, almost all incentives (sexual favors, better rooms, etc) can be considered undue influence because of the significant power between [REM12] the incarcerated participants and researchers. There is another famous example of the Willowbrook School, where parents were encouraged to enroll their mentally retarded children into a hepatitis research project in exchange for admission into a highly competitive residential facility for the children. In this case, the vulnerable populations were both the children who were often too young and mentally incompetent to make autonomous decisions, and the desperate parents who were subject to the undue influence of admission to the facility to make a decision that might have gone against their better judgment.

On the other hand, it is important to remember that, for some research participants, the various incentives gained from research are an invaluable source of income and other benefits. A fellow third year medical student is currently conducting HIV- research in the Dominican Republic, and her population of interest is sex workers; for these workers, the only way to incentivize them to participate in this research is to reimburse them for their time, and it is also an opportunity to provide valuable antiretroviral medication and education [REM13]. Additionally, there is a lot of important medical and epidemiological knowledge to be gained from HSR, which often justifies the use of incentives to boost enrollment in studies, even in vulnerable populations.

Thus, in these various situations, it is crucial for the researcher to respect and understand the values and beliefs of the populations they are enrolling

and studying. The research team must be sensitive and aware that some incentives may be simply too good to refuse for certain vulnerable populations, and that these people might be acting against their better judgment to participate in research. This sensitivity may require the team to abstain from offering lucrative and tempting offers to vulnerable participants in high-risk and low-reward research settings, even though the enrollment potential of the study may be therefore limited [REM14].

The last principle left to discuss in the context of vulnerable populations is that of justice, especially in the context of fairness in the subject selection. In this case, the populations that are most likely to be affected are either the poor sector, or ethnic minorities. This is due to the fact that people of a low socioeconomic status are sometimes more likely to be targeted and exploited for research participations, due to a potentially lower cost of incentives for certain studies. The converse can also be true when testing out advanced medical innovations where people who are of a lower socioeconomic status or have less access to medical care might not initially be recruited to the benefits of such a study. Another interesting issue that has arisen due to the US history of mistreatment of certain minorities (most notably African-Americans in the Tuskegee syphilis experiments) is that there is a certain level of mistrust among minority populations towards human subjects research.[4] However, in order to adhere to the principle of justice, there must be fairness in subject selections as well as equal access to the benefits of research. Due to misdeeds of the past, these seeds of mistrust can prevent certain groups from participating in research, and one of the easier solutions is to offer greater compensation in order to elicit

participation. This practice is not fair, since some subjects are receiving greater compensation in order to convince them to participate in studies, and this can blur the ethical lines of both respect for persons as well as justice. This is a yet unresolved issue; on the one hand, we need subjects of different races and ethnicities to participate, but it is not fair to compensate certain subjects differently as compared to others. The greater issue here is to heal the rift and historical mistrust that has developed over years of mistreatment of certain populations, and to treat all participants with maximal respect when enrolling for studies[REM15].

In conclusion, there are no easy answers when it comes to determining the ethics of incentives. The most important point to consider is that each individual has different sets of values, beliefs, and backgrounds, and it is up to the research team to be diligent about informed consent, autonomy, and education. If researchers are sensitive to the financial, socioeconomic, and various hierarchical power differentials that they may encounter in the process of enrolling patients in studies, then there can be a more open and honest discussion with the participants about the risks and benefits of participating in research, even when there are incentives offered. In this way, we can make sure that our patients are not being coerced into participating in HSR, but are able to contribute to society in a meaningful way that does not conflict with their inner ideals[REM16].

[1]“ Concise Oxford English Dictionary.” *Concise Oxford English Dictionary* . Ed. Angus Stevenson and Maurice Vaite. N. p.: Oxford UP, 2011. 1575. *Google Books* . Web. 16 Apr. 2015.

[2]The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* . Rep. N. p.: n. p., 1979. *US Department of Health and Human Services* . Web. 17 Apr. 2015

[3]Emanuel, E. J., D. Wendler, and C. Grady. “ What Makes Clinical Research Ethical?” *JAMA* 283. 20 (2000): 2701-711. *JAMA Network* . Web. 17 Apr. 2015.

[4]Grant, R. W., and J. Sugarman. “ Ethics in Human Subjects Research: Do Incentives Matter?” *Journal of Medicine and Philosophy* 26. 9 (2004): 717-38. Web.

[REM1]I’m not sure it’s uncharted. There’s been lots of discussion, but there isn’t a clear consensus. So perhaps “ uncertain territory” fits better.

[REM2]It’s fussy, but it’s not the ethics (those are more constant), but rather the issues related to compensation that often boil down to the patient population.

[REM3]Critical – what makes it “ undue” – let’s see...

[REM4]I hope you pick up that in many cases the influencing factors in cases of vulnerable subjects are meant to induce the signatory agent, who may not be the research subject. Separate influencing the subject and influencing the decision maker.

[REM5]Much more than that – it’s the right of the individual to control their own life, to make the decisions that matter to how their life will proceed.

[REM6]Maybe “ hierarchy” would be better. “ Dichotomy” implies a binary split – it’s correct, but less flexible.

[REM7]This notion seems abstractly reasonable, but might there be some dispute as what represents the best interest of the patient/subject? Does trying to sway someone from one beneficial study to another constitute influencing, perhaps undue?

[REM8]I think you could state this more clearly.

[REM9]Forced? Or desirous of participating in order to achieve the financial gains?

[REM10]Hmm – how would you feel if I offered you \$15, 000 to participate in research? I don’t consider you vulnerable, but would this make you willing to accept risks that you otherwise might not?

[REM11]A classic is bribing parents to “ buy” child research subjects. Diapers work well....

The worry is that even with beneficent research, there may be choices, and the vulnerable subject may not be able to navigate the choices well.

Beneficence in-and-of-itself is not sufficient to decrease the worry related to undue influence.

[REM12]Power differential between

[REM13]That's a great case! You can see the potential of the incentives for good – but for those who think the decision to participate in research should be independent of anything other than the intrinsic value of the research, it's undue inducement (a point with which I do not agree)

[REM14]You've made a decision that's different than the purists I described in the last comment would favor.

[REM15]Demonstrating that truly achieving justice can be a complicated matter.

[REM16]Conceptually, you were on the right track, but your discussion isn't very nuanced.