EVALUATING THE IMPACT OF INCENTIVES ON CLINICAL TRIAL PARTICIPATION

By

Brandon Philip Nguyen

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APPROVED

Dr. Brandon Brown

Department of Social Medicine, Population and Public Health

Dr. Richard Cardullo, Howard H Hays Jr. Chair

University Honors

ABSTRACT

Monetary incentives in research are frequently used to support participant recruitment and retention. However, there are scant empirical data regarding how researchers decide upon the type and amount of incentives offered. Likewise, there is little guidance to assist study investigators and institutional review boards (IRBs) in their decision-making on incentives. Monetary incentives, in addition to other factors such as the risk of harm or other intangible benefits, guide individuals' decisions to enroll in research studies. These factors emphasize the need for evidence-informed guidance for study investigators and IRBs when determining the type and amount of incentives to provide to research participants.

The specific aims of our research project are to (1) characterize key stakeholders' views on and assessments of incentives in biomedical HIV research; (2) reach consensus among stakeholders on the factors that are considered when choosing research incentives, including consensus on the relative importance of such factors; and (3) pilot-test the use of the guidance developed via aims 1 and 2 by presenting stakeholders with vignettes of hypothetical research studies for which they will choose corresponding incentive types.

By studying the role of incentives in HIV clinical trial participation, we will establish a decision-making paradigm to guide the choice of incentives for HIV research and, eventually, other types of similar research and facilitate the ethical recruitment of clinical research participants.

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INTRODUCTION

Providing incentives, which is defined as "Payment [including money, gifts, and services] to research subjects for participation in studies"[1], is accepted and often practiced in HIV clinical research [2-5]. Although some studies suggest a strong altruistic motivation for participation [6-8], incentives are typically necessary to ensure enrollment in research [5, 9], including high-risk trials and other studies that may lead to negative participant health outcomes [10]. In addition, acquiring access to care and advanced diagnostic tests not otherwise available could also be viewed as incentives, which raises concerns about undue influence [8, 11]. Although it's known that incentives provided among similar studies can greatly vary [5, 12], surprisingly little research exists on factors considered when deciding on appropriate incentives.

Incentives and Study Risks/Benefits

The risks, benefits, and burdens for a research participant may significantly change depending on study type and procedures, which could affect payment. Furthermore, we know research payment practices are inconsistent and can vary greatly [5, 13]. Many factors, such as risks and benefits, historical precedent, study procedures, time commitment, study budget, IRB recommendations, advice from other investigators, and local regulations, influence decisions regarding appropriate research incentives. These factors lead many researchers to ponder what appropriate incentives are for their study. The answer to this question is continuously debated and difficult to answer. HIV treatment and cure-related research demonstrate this issue in that participants could face greater than minimal risk (e.g., drug resistance); the outlook for direct individual benefit is low; and participants could face additional social vulnerabilities (e.g., belonging to a sexual minority, having lower SES) all of which can affect their motivation to participate [6, 12, 14, 15].

Difficulties in Determining Incentive Amounts

Ideally, incentives encourage participation and participant retention for clinical and behavioral research without causing undue inducement [9, 16, 17]. However, finding a balance between incentive type and the amount is difficult to establish when significant variability exists across studies. One possible factor in this variability is the spectrum of researcher attitudes regarding the ethics of incentives and beliefs about what the IRB will permit, which is reflected in the monetary amounts approved by IRBs across similar protocols even at the same institution [5]. Other factors could include features of the research study and participant setting characteristics, such as local norms and cost of living, as well as variability in institutional practices. For example, the most recent comprehensive study of payment in U.S. research (2005) described 467 publications of clinical studies, where fewer than 25% reported payment amounts [5, 18]. Furthermore, a review by Dickert [19] showed that fewer than one-fifth of U.S. institutions knew which of their studies provided payment. Even when institutions track payment, significant differences often exist in IRB understanding of undue influence, which is sparsely studied [5, 20, 21].

The Impact of Incentives on Study Participation

According to relevant literature, there is not much known about the actual effects of incentives on clinical research participation. Furthermore, it is difficult to track the use of incentives in research especially since investigators are not required to record their payments to participate [70]. Dr. Brandon Brown demonstrates in this IRB article why it is necessary to not only study incentives and their impact but also track the payment that investigators give out. Our study

seeks to fill this gap in knowledge so that researchers in other fields can come to more guided decisions regarding payment to their participants. Further, incentives are not systematically tracked to permit comparison and reference for new studies. In the absence of such data, equality of incentives across similar studies is impossible to determine [30]. To control over- and under-incentivizing, South Africa developed standardized payments for participants [31], and Brazil prohibits all monetary payments for clinical trials [32]. Outside of these rare cases, the absence of a reference for comparison burdens researchers to determine appropriate incentives on a case-by-case basis. Decisions on acceptable payment should not be made without a clear understanding of currently offered incentives or else we will continue to utilize personal biases without critical assessment.

Undue inducement

An important topic will be defining "undue inducement" from the perspectives of key informants. We will ask each category of informants to define what they consider "undue inducement" and compare perceptions with current guidelines. Since some people may not have a well-defined sense of what 'undue inducement' is, we will provide some examples and encourage discussion of ethically worrisome scenarios. We will also examine how incentives may relate to risks and whether they are perceived as signals of the risks in clinical research [41]. The CIOMS guidelines state: "Compensation is not meant to compensate for the risk that participants agree to undertake." It is possible, however, that stakeholders still perceive that incentives should compensate for risk and that payments are a way of making risks acceptable to participants [6]. We will explore ethical issues related to this topic, and also consider incentives that may be viewed as too small. Further, we are interested to know if key informants perceive

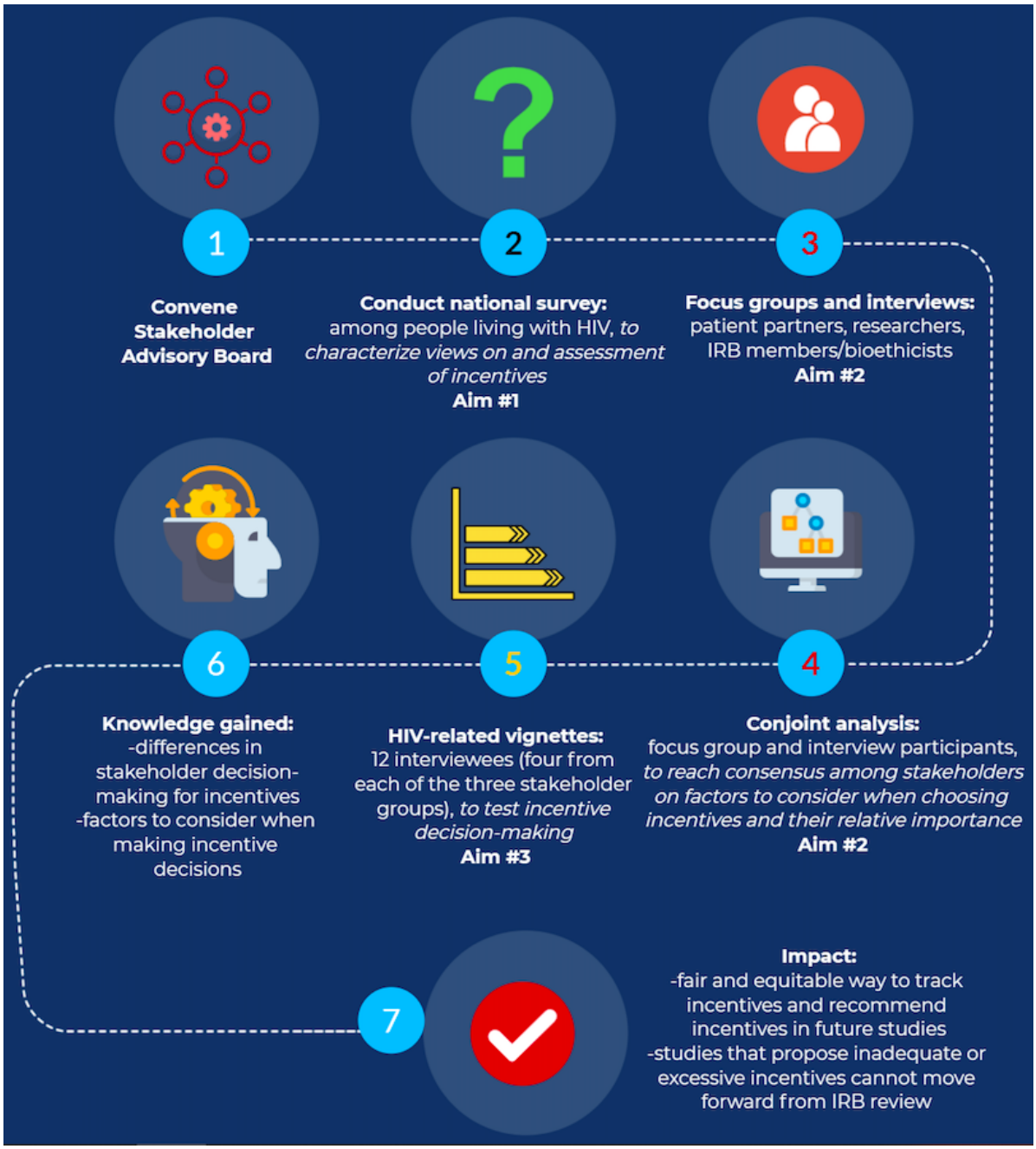
incentives as a benefit of research participation. Federal law expressly prohibits consideration of compensation as a benefit to offset risks [4]. This is because of concerns that a very risky study may be seen as having an acceptable risk-benefit ratio simply by paying a lot of money. It is possible, however, that patients still consider money to be a benefit of research participation, at least beyond reimbursement. Do incentives make the perceived risk-benefit ratio more favorable or acceptable [6]? Do they affect the perceived balance of risks and potential benefits? [42] There may be ethical issues when incentives sway the decision-making capacities of individuals by making them ignore the risks involved, versus balancing the risks and benefits [43]. We will further ask for specific recommendations to improve the description of payments in informed consent.

Study Aims

Our specific aims are to: characterize key stakeholders' views on and assessment of incentives, reach consensus among stakeholders on the factors to be considered when choosing incentives and their relative importance, and pilot test using vignettes for incentive decision making. The projected outcomes resulting from the aims are the determination of different stakeholder groups' views about incentives, shared decision making on relevant parameters to collect, and understanding of how well our chosen factors can predict incentive decision making.

METHODS

Overview and Study Design



Key Study Questions:

We will use MTurk surveys, CJA, focus groups, interviews, and hypothetical scenarios to ask the three groups of stakeholders about:

a. Current perceptions of research incentives
b. How incentives may provide an undue inducement
c. Perceptions on how incentives influence willingness to participate in research
d. Beliefs about the impact of having access to transparent incentives from existing studies
e. Beliefs about whether incentives are too high and if this leads to low-quality data and decreased value of results

Study Duration and Timeline

The total duration of the study is 24 months, including time developing an advisory board, recruitment, and conduct of the focus groups and interviews, vignette piloting, data analysis, and publication. We also received IRB approval and review in this period. See **Table 2** for a timeline overview of the research project.

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Participants and Recruitment

We will have a 10-member community advisory board made up of IRB members, community members, and those in academics. We meet once each month for 1.5 hours and these individuals are compensated with $30 for each meeting.

As for recruitment, we will recruit patient partners, biomedical HIV researchers, and Institutional Review Board (IRB) members/policy-makers/bioethicists involved in HIV research and HIV comorbidities. Comorbidities are medical conditions that are simultaneously present with others in a patient. In this situation, the comorbidities often associated with HIV are depression, heart disease, and arthritis. For the patient populations, we will target men including men who have sex with men (MSM) and women aging with HIV, cis and transgender women, and youth (age 18+) of color. Protocol Synopsis: We plan to conduct the survey, key informant interviews, and focus groups in the following manner:

Nationwide quantitative survey with ≥ 300 patient representatives to obtain perceptions on how incentive decisions are made, what incentives qualify as appropriate, and whether incentives impact decision making. We will hold ≥12 key informant interviews with patient partners from throughout the U. S. to obtain perceptions on the ethics of incentives in research (patient partners will be selected from survey respondents). We will hold ≥12 in-depth interviews with biomedical HIV researchers to obtain perceptions on the ethics of incentives in research (or until thematic saturation). We will hold ≥12 in-depth interviews with IRB members/policy-makers/bioethicists to obtain perceptions on the ethics of incentives in research (or until thematic saturation). We will have 4 focus groups with patient partners (8 – 10 people each) at various locations in the U. S. to obtain perceptions on the ethics of incentives in research (or until thematic saturation).

Data Collection

Quantitative Survey

In the first phase, we will implement a cross-sectional, internet-based, semi-structured survey (n ≥ 300 patient representatives) to assess how incentives affect willingness to participate in research. The survey will be done through Amazon MTurk, it will take approximately 20 minutes for participants to complete, and participants can skip any questions that they feel uncomfortable answering (**Table 4**). In addition, the survey participants recruited via MTurk will receive $10 compensation. Respondents will be HIV treatment and cure research participants and HIV patients with depression, heart disease, and arthritis issues. This purposive national sample will represent patient partners who are diverse in age, gender, sexual orientation, race/ethnicity, time since diagnosis, and history of participation in clinical studies. We will perform standard descriptive, bivariate, and multivariate analyses on survey data.

Focus Groups

We will hold in-person focus groups with patient partners. Each focus group will last approximately 1 hour and 40 minutes, will be conducted using HIPAA-compliant Zoom, and be video recorded. Participants without sufficient technology for video streaming will be permitted to call for the discussion. In addition, the focus group participants will each receive $25 compensation. We will develop reciprocal relationships with focus group participants by employing a 'give and take' approach, using fact sheets. A key advantage of focus groups is that they help evoke conversation [49]; however, they may foster groupthink. We will mitigate this drawback by having a strong leader trained in facilitating focus groups effectively to ensure input from all members and minimize irrelevant discussion and people speaking over each other. This, in turn, will facilitate transcriptions and enable the decipherability of audio data. We will ensure

uniformity in the administration of focus groups. Our questioning route will mirror key domains in the survey and the interviews to allow triangulation of data (**Figure 5**). The EAB will review the focus group script before IRB submission and implementation.

Interviews

We will conduct key informant interviews with patient partners, biomedical HIV researchers, and IRB members/policy-makers/bioethicists to obtain their expert opinions and understand their perceptions of incentives. Each interview will last approximately 1 hour, will be conducted using HIPAA-compliant Zoom, and be audio recorded. In addition, the interview participants will each receive $25 compensation. Professional informants (e.g., biomedical researchers and IRB members/policy-makers/bioethicists) will be interviewed one-on-one as we believe they will find this modality more convenient than focus groups, and they will be free to share information. Key informant interviews also have high data yield, are easier to coordinate and transcribe, and permit the collection of information from knowledgeable individuals as well as the flexibility to explore emerging themes [46-48]. We will develop and adapt informed consent forms and interview guides for each category of key informants. The EAB will review the guides before IRB submission and implementation.

Vignettes

Once we have the 6 to– 8 features from Aim 2, and the final number of choices (2 – 3) per feature, we will use a factorial design to create 25 vignettes (hypothetical scenarios) which will each last approximately 10 minutes. For instance, if feature A has two choices (A1, A2), and feature B has three choices (B1, B2, B3), then the two features together give rise to six

combinations (A1B1, A1B2, A1B3, A2B1, A2B2, A2B3) under a factorial design. Incentive amounts in each scenario will be chosen to make the questions meaningful and informative. They should not be so large or so small that the answers are almost unanimous and therefore predictable. The three quartiles of actual research incentives in the specified area may be reasonable choices, with $500 as the first amount presented. A range of 0 up to $20,000 is consistent with studies we have identified in the literature. With information from Aim 1 and 2, the EAB will develop the HIV-related vignettes (hypothetical scenarios) [67-69]. These vignettes will be based on studies identified in the literature and a review of consent forms and created in conjunction with the EAB (including pre-testing and revision before finalization). We will contrast different types of HIV studies, varying parameters such as 1) intervention tested, 2) perceived risks, 3) participant population, and 4) inconvenience of study visits, etc. We will also integrate the 3 co-morbidities (depression, heart disease, and arthritis) into the vignettes. Individuals from each group will select the most appropriate incentive from a list of possibilities based on various scenarios (**Table 3**). Participants pilot testing the vignettes will each receive a $50 compensation.

Data Analysis

The main goal of data analysis will be to generate a list of factors that key informants deem important to consider when thinking about incentives in HIV research. Qualitative analysis will rely primarily on grounded theory, which seeks to understand the realities grounded in the views of the study participants [50]. We will develop a codebook to analyze the data, and use a combination of a priori (or existing, pre-determined) codes and data-driven (or emergent, latent) codes [50, 51]. Code development will be an iterative process. As relationships between different

themes and sub-themes become evident, narratives will be combined into general concepts, summarizing key informants' perceptions. We will use the MAXDQA software (version 12.1.3, Berlin, Germany) for analysis.

Analyzing Focus Groups and Interviews

Following the focus groups, we will use CJA to empirically measure the influence that specific incentive amounts (as well as other study characteristics) have on the decision to participate. CJA will be done within the same Zoom session and last approximately 10 minutes. There will be no separate consent for CJA, but we have included CJA in the consent and called it a hypothetical study discussion. To execute CJA, we will present participants (as a group) with multiple, hypothetical studies in which they could participate (or approve) in the Zoom meeting. Each hypothetical study will be presented as a finite set of characteristics that vary in value. Participants will demonstrate their preferences for these studies by completing exercises that force trade-offs between similar studies with the same characteristics but different values. CJA will be conducted in 2 stages. In the first stage, participants will sort the hypothetical studies (on a printed card) based on their likelihood of approving the study by scoring each card on a scale from 1 ('definitely would') to 5 ('definitely would not'). In the second stage, participants will rank the same studies/scenarios presented in the first stage by sorting the cards from first place ('most likely to approve/participate') to last place ('least likely to approve/participate'); the scenarios will be presented randomly to prevent order effect bias.

Analyzing MTurk Surveys

All participants apart from those participating in the MTurk survey (interviews, focus groups, pilot of vignettes) will fill out a short demographic survey that will be linked to their confidential responses for understanding differences in study data by key demographic variables of participants. This demographic survey will
be completed after consent and immediately before the study procedures mentioned above (interviews, focus groups, vignettes). In this way, we will only collect survey data from participants who show up for the study procedures.

Conjoint Analysis

Conjoint Analysis (CJA) is a consumer market-based methodology developed in the 1970s designed specifically for the task of determining which characteristics most influence a consumer's decision to purchase a product or service and follows two fundamental assumptions: 1. When choosing between very similar products/services, consumers make choices based on the interconnected (i.e. conjoined) characteristics that make up the products/services and make tradeoffs between the characteristics leading to a product preference. 2. Consumers make product/service preferences rationally and preferentially select products/services that increase personal benefit and minimize personal costs (the theory of random utility maximization) [52]. We consider patient partners as "consumers" and research projects "products or services", and when deciding whether to participate in a research project, potential subjects make trade-offs between the various study characteristics in a rational way to increase their benefit and decrease

their costs. CJA is methodologically well-suited to this Aim as it has an efficient statistical methodology that allows the estimation of the influence of the various factors with small sample sizes and allows the model fit to be tested empirically [53, 54]. Further, CJA has been used to effectively predict preferences and acceptability for a wide range of medical issues, from disease treatment to health care systems [55-62], and can predict "real-world outcomes" such as patients' actual HIV medication choices [63]. CJA has been used in the assessment of hypothetical biomedical HIV interventions [64-66].

The ability of CJA to accurately reflect and predict consumer preferences is heavily dependent on the type of person participating in the CJA experiment and the selection of the study characteristics (and their values). Participants in our CJA experiments will be people who have or would consider participating in biomedical research, increasing the generalizability of the results to a real-world setting. To determine the study characteristics for the CJA experiments, we will choose those that are the most common and applicable for multiple types of studies by convening the EAB to develop all possible study characteristics that may impact a choice to participate in the study. Each characteristic will also have different values from which participants must choose, for example, the "risk" characteristic may have three values: "no risk," "minimal risk" and "moderate risk" whereas the incentive received per study visit characteristic may have the values "none", "$50" or "$100." The characteristics and values used in our CJA exercises will be arrived at after extensive consultation with researchers and IRB chairs, as well as review of relevant research literature.

The application of CJA is straightforward: we will present participants with multiple, hypothetical studies in which they could participate (or approve). Each hypothetical study will be presented as a finite set of characteristics that vary in value (e.g., **Table 1**). Participants will demonstrate their preferences for these studies by completing exercises that force trade-offs between similar studies with the same characteristics but different values. This will produce a unidimensional interval-level scale of benefit importance based on nominal level choice data (i.e. most important versus least important). CJA will be conducted in 2 stages. In the first stage, participants will sort the hypothetical studies (on a printed card) based on their likelihood of approving the study by scoring each card on a scale from 1 ('definitely would') to 5 ('definitely would not'); in this exercise, multiple studies/scenarios may share the same rating. This stage will allow us to independently rank order the acceptability of each of the hypothetical scenarios. In the second stage, participants will rank the same studies/scenarios presented in the first stage by sorting the cards from first place ('most likely to approve/participate') to last place ('least likely to approve/participate'); the scenarios will be presented randomly to prevent order effect bias. In contrast to the first stage, the hypothetical studies cannot be identically scored; participants must choose the most preferred scenario, followed by the next most preferred scenario, and so on. This stage will allow us to estimate the relative influence that each attribute had on the choice of each hypothetical study. Data from both CJA exercises will be used alongside the data from Aim 1 to construct the model in Aim 3.

DISCUSSION

Conclusions

With the aforementioned lack of guidelines regarding payment in research, it is also a goal of our study to investigate how researchers and participants view the use of incentives. To accomplish this, we will create vignettes, and hypothetical scenarios, in which we can observe what factors influence the individual decisions on participating in a research study. Through our research, we want our findings to provide data that can help inform future ethical payment practices.

ABBREVIATIONS

HIV: Human Immunodeficiency Virus

MSM: Men who have Sex with Men

PLWH: People Living With HIV

IRB: Institutional Review Board

CJA: Conjoint Analysis

EAB: External Advisory Board

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