

Using decision theory for analyzing enrollment in a scientific study in the health area

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ABSTRACT

This article explores the current literature about the factors that lead people to enroll in a scientific study in the area of health. Recruitment of participants has been shown to be a problem with the number of participants willing to participate decreasing widely. For this reason, it is important to understand how and why people make the decision to participate in a scientific study, in order to develop mechanisms that counteract this tendency. For that purpose, a review of current literature was conducted and the evidence was related with decision theory. The goal is to understand how the decision process to participate in a study occurs and which actions can be taken to maximize the recruitment process.

1. INTRODUCTION

One common problem in health research is the difficulty to recruit and maintain participants during all the phases of a study. Recent data suggests that participation rates among individuals of different ages, even those most represented in epidemiologic clinic investigation, fell into levels that can endanger some research areas (Galea & Tracy, 2007). Therefore, we are trying to understand the variables and mechanisms related to the recruitment process and the involved decision-making process to participate in such studies.

In the healthcare setting, high impact decisions that affect people's well-being and quality of life are often taken. In this area, emphasis on research has been growing and focuses essentially on experimental research (Sanders & Haines, 2006; Sim & Wright, 2000), or in other words, in the improvement and development of therapeutic strategies and rehabilitation. Financial investment has been important and substantial in areas such as drugs and vaccines. However, one of the main reasons that pushed research in health was the need of "evidence-based practice". This philosophy is one of the basis of decision making by the majority of health practitioners, which is based in using therapeutic strategies that have been validated and their efficacy scientifically proven, instead of grounding their practice in personal experience, clinic intuition or more traditional proceedings (Sim & Wright, 2000). For this reason, "evidence-based practice" is directly related to research, as it does not depend on opinions, values, preferences or expectations. For this kind of research to happen, it is necessary to recruit people, given that most of research in this area is intimately related with the human being. Therefore, people have an important impact in this field of research and are also those who benefit from the health services, which we want to be the more efficient as possible. Thus, it is important not only to increase the amount of research, but mainly the proportion of people that enroll in studies (Salmon et al., 2007). This is an international priority (Lionis et al., 2004).

In the literature, there are several references about the difficulties and barriers faced when recruiting participants for scientific ends, among them we can mention the way possible participants are approached (Hewison & Haines, 2006) and belonging to a minority group (racial and ethnic minorities, elderly, children, rural residents, people with low socio-economical level) (Ford et al., 2008).

In this work, we reviewed the literature in order to understand which mechanisms/variables work as barriers/facilitators to the enrollment in scientific studies related to health. We aim to cross this information with decision theory in order to understand how we can increase chances of having success when recruiting participants.

2. Barriers to Participation

According to Ford et al. (2008), for a person to accept/refuse to participate in a clinic trial, he/she has first to be aware that it is happening (Awareness) and then needs to have an opportunity to participate (Opportunity). After having the opportunity to participate, the individual can look for information about potential risks and benefits of a possible participation (Acceptance/Refusal). This conceptual model also reports an association between specific factors and the decision not to participate, specifically; (1) Apparent physical pain/discomfort from participating in the trial; (2) Loss of control (uncertainty about group allocation during the treatment); (3) Nature of the intervention; (4) Time of intervention; (5) Salary loss (by missing work); and (6) Transport.

Interestingly, the number of people that agree to participate in a study is much bigger when they are approached directly by the researcher than when people have to take the initiative to participate and approach the researcher with that purpose (Hewison & Haines, 2006). The same authors criticize the actual recruitment approaches and suggest other practices highlighting some participants particularities. For example, many participants do not want a detailed explanation about methodological issues such as problems caused by biased samples. These authors also defend that people prefer to be sure that the research topic has quality and is relevant and judged by fair and impartial elements. Additionally, the contribution of participants must be valued and appreciated. Specific constraints for participation are: (1) Most of the times health research is a novel topic for many participants; (2) Few will understand its scientific basis; (3) Many people do not realize the importance of a high participation rate and can conclude that their participation is not necessary; (4) Erroneously assume that their participation is not useful because they consider that only ‘typical’ participants will be desired; (5) To have prior hostile preconceptions due to previous experiences or events related to research; and (6) Difficulties in reading, writing or walking.

Ejiogu et al. (2011) conducted a longitudinal study over 20 years to identify and rectify participation barriers in scientific studies in order to recruit and maintain participants during all phase of a study. The authors worked with a bi-racial sample (Afro-Americans and Non-Hispanics whites) with diverse socio-economical levels. Three barrier domains (individuals, community, and researcher and scientific), respective subdomains and solutions to overcome these barriers were identified. As second and third domains are not directly related with the individual, we will not discuss them, however, they have indirect influence when choosing to participate in a study. From the several subdomains, we emphasize the ones we particularly experience in our practice, such as transportation, economic constraints, behavioral & social factors. The solutions encountered for transportation were to provide free transport or neighborhood presence, flexibility and compensations for economic constraints, and none for behavioral & social factors. The conclusions focused in the main solutions found to recruit and keep minorities or economically poor participants during all the process: (1) Research hypothesis clearly communicated; (2) Provide a direct benefit to participants; and (3) Selection of a hypothesis that is directly relevant to the studied community.

Galea & Tracy (2007) elaborated a literature review to understand the reasons behind the decrease over time of participants’ adherence in scientific studies. These authors identified four possible reasons that help to explain this phenomenon. The first is the proliferation of scientific studies, both academical and governmental, which we have witnessed in the last decades. The second reason is the decrease in voluntarism that contributes for lower motivation in volunteer involvement. The third cause is the fact a specific study might not bring any direct or immediate benefit to the participant. A fourth reason has to do with the own nature of studies, namely the ethical criteria and phases that constitute a study such as informed consent, several moments of intervention, long assessments and follow-up. All these reasons increase the tendency to people rejecting to get involved because they assume or feel that it is too much exhausting and will consume too much of their time.

Another systematic review by Ross et al. (1999) corroborates some barriers that recent studies have also identified. On their conclusions, the authors refer that additional demands from a study can influence the decision to participate or even lead to drop-outs. Problems like transportation or the costs associated were also identified as causes that lead to avoid participation, miss a session or drop-outs. In contrast, the authors observed that the most common motivation to participate is altruism. However, there are other factors that seem to contribute such as: (1) Counseling from someone important (familiar, close friend, wife/husband); (2) Recruitment by medical doctors; and (3) Good relationship with researchers.

3. Decision Theory and Utility Function

Decision theory (for an overview see (Resnik, 1987)) is a research area that studies how individuals or groups of individuals make decisions. Almost everything that a human being does involves decisions. However, decision theory studies the situations where there are options to choose from, and these options are chosen in a non-random way. In this situation, the choices are *goal-directed* in the sense that they maximize the outcome utility. Utility is a measure of preference over an outcome. This measure can be objective (e.g. amount of money) or subjective

(e.g. grade of satisfaction). We can divide the decision in three big groups: “decision under certainty”, where the agent knows the consequence of his decision; “decision under risk”, where the individual knows his decision will result in a given outcome with a certain probability; and “decision under ignorance”, where the individual knows the possible outcomes of his decision but ignores the probability of each of them. Therefore, in this paper, we will focus in decision under ignorance as it is what happens when people accept or decide to participate on a health study.

There are several strategies to increase outcome utility with decisions under ignorance. One can value different aspects such as Maximin Rule, Minimax Regret Rule, Optimism-pessimism Rule and the Insufficient Reason Principle (Briggs, 2014). All them can produce different choices, and given we are under ignorance, there is no alternative that maximizes all the techniques. Hence, there is no obvious choice. The Insufficient Reason Principle seems to be the most reasonable to be used in this particular situation, since it is based on the principle that under ignorance different probabilities among the states (barriers/facilitators) are not evident. Therefore, we assume all as being equally likely. Anyhow, this principle can be seen as an attempt of making a decision under ignorance in a decision under risk. Laplace declared this principle as “reducing all the events of the same kind to a certain number of cases equally possible, that is to say, to such as we may be equally undecided about in regard to their existence, and in determining the number of cases favorable to the event whose probability is sought. The ratio of this number to that of all the cases possible is the measure of this probability, which is thus simply a fraction whose numerator is the number of favorable cases and whose denominator is the number of all the cases possible.”(Laplace, 2012).

To calculate the best decision, we did a weighted average multiplying the value of the item attributed utility by the item expected personal utility. Accordingly, the most likely choice must fall over the one that shows the highest value, meaning a higher utility. Therefore, we created a model case of a possible participant in a health research study.

3.1. Model Case

To test the choice between to participate or not to participate in a health research study, we created a model case attributing some characteristics that would be acceptable a male with 50 years to have:

- Male;
- 50 years old;
- Stable job with a 2500€/month salary;
- No familial obligations;
- Can freely manage his work time;
- Recent cancer diagnosis.

We have chosen 4 barriers and 2 facilitators, and associated utility values to each one. A prediction of personal utility values according to the profile of the case model were attributed (Table 1). These values vary between “0” and “1”, with 0.5 meaning a utility without impact. A value below this means a negative impact, and above means a positive impact. The further values are from 0.5, the bigger the impact that must be assumed. It should be noted that these values were attributed according to the profile created, meaning that is something very personal and that can change between different circumstances. For example, what is a barrier for one person can be considered a facilitator for another. After calculating the utility just with barriers (Ejiogu et al., 2011; Galea & Tracy, 2007; Ross et al., 1999), we got a value of 0.41 to “Participate” and 0.40 to “Not participate”. Hence, while the difference is minimal it still compensates to “Participate”. Next, we included two facilitators. This way, we should expect a large increase in the “To participate” ratio compared to “To not participate”. After we included the facilitators, the difference between the two values is more considerable, with 1.43 to “Participate” and 1.16 to “Not participate”, which makes the decision of participating almost 25% better than not to participate.

Actions		Participation		Non-participation	
		Item value	Item attributed value	Item value	Item attributed value
Barriers	Wage loss	0.1	0.4	0.1	0.5
	Without self-transportation	0.3	0.5	0.3	0.5
	Intervention time (time spent)	0.2	0.7	0.2	0.4
	Possibility of slight pain as a consequence of study participation	0.2	0.4	0.2	0.6
		0.41		0.4	
Facilitators	Financial benefit to cover costs and time spent	0.8	0.6	0.8	0.5
	Research in new cancer therapies	0.9	0.6	0.9	0.4
		1.43		1.16	

Table 1. Simulation of some possible barriers and facilitators identified by the literature related to the participation in health research. Each item was attributed a utility and an expected personal utility.

4. CONCLUSIONS

Recruitment proceedings are part of science and not an administrative component. In order to contribute to health services development, recruitment proceedings need to reduce the factors that have the potential to lead possible participants to refuse participation in a study. Given that the decision to participate in research is probably determined by trusty perceptions, benefit, and justice, communication with possible participants should not be ignored. Communication should be robust and strategic, explaining why the use of personal information is important and needed for research, in order to promote higher participation rates.

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