A Survey of Patients’ Attitudes to Clinical Research

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Abstract
Every year hundreds of patients voluntarily participate in clinical trials across Ireland. However, little research has been done as to how patients find the experience. This survey was conducted in an attempt to ascertain clinical trial participants’ views on their experience of participating in a clinical trial and to see and how clinical trial participation can be improved. One hundred and sixty-six clinical trial participants who had recently completed a global phase IV cardiovascular endpoint clinical trial were sent a 3-page questionnaire. Ninety-one (91%) respondents found the experience of participating in a clinical trial a good one with 85 (84.16%) respondents saying they would recommend participating in a clinical trial to a friend or relative and eighty-five (87.63%) respondents feeling they received better healthcare because they had participated in a clinical trial.

Introduction
It is very important that the experience of being in a clinical trial is a good one for the patient, as this encourages participation in future clinical trials, which is the corner stone of medical therapy advancement. Therefore, it is crucial we learn how previous trial participants view their experience and how that experience can be improved for future clinical trials. One hundred and sixty-six people who had recently completed their participation in a global phase IV long-term cardiovascular endpoint clinical trial [Ongoing Telmisartan Alone and in combination with Ramipril Global Endpoint Trial (ONTARGET)] were sent a 3-page questionnaire. The questionnaires were sent to the patients at the four participating Irish sites. ONTARGET evaluated a patient population at high risk for vascular events and included patients with coronary, peripheral or cerebrovascular disease or diabetes with end-organ damage. The mean age of the ONTARGET study participants was 66.4 years with 18,789 (73.3%) of the participants being male. Complete information on the patient demographics has been published.

Methods
The trial participants were asked to complete a 3-page questionnaire. The questionnaire collected no information that could identify a respondent and hence the returned completed questionnaires were completely anonymous. The questionnaires and the survey were approved by the ethics committee of each hospital which participated in the ONTARGET trial. The questionnaire captured basic demographic information (age group was defined by protocol as >55 years), the patients’ views on clinical trials before they participated in this trial, the reason they participated, their view on clinical research subsequent to their participation, ways the experience could be improved, if they thought they received better health care as a result of participating in the trial, if they would participate in a trial again, give consent for a child to participate or advise a friend or relative to participate. The questionnaire also contains questions on whether or not patients had ever heard of an ethics committee (IRB/IEC) or the local national regulatory body i.e. the Irish Medicines Board (IMB). The results of the answer to each question are expressed as the number of responses and as a percentage of total.

Results
A total of 166 questionnaires were mailed to the Irish ONTARGET clinical trial participants. Of these 100 questionnaires were returned, giving a response rate of 60.24 %. Eighty-six (86%) respondents were male and all were >55 years of age. This demography reflects the ONTARGET clinical trial population. When asked whether they had ever heard of a clinical trial prior to taking part in ONTARGET, 43 (43%) respondents indicated that they had. Table 1 documents the respondents view of clinical trials prior to participating in a clinical trial. Sixty-five (58.25%) people thought clinical trials were valuable medical research, while 12 (11.65%) respondents thought you were a "guinea pig" if you took part in a clinical trial. Thirty (28.13%) people indicated that they did not have an opinion on clinical research and 1 person (1%) indicated that they did not remember their opinion.

The respondents were asked why they decided to participate in the ONTARGET trial (Table 2). Fifty-one (42.5%) respondents indicated that they participated to get close monitoring of their illness. Thirty-three (27.5%) respondents indicated that they participated to get close monitoring of their illness.
respondents indicated that they participated in the clinical trial to help others and because their doctor suggested it. Three (2.5%) respondents indicated they participated in ONTARGET to get access to study treatments. Table 3 shows how the ONTARGET participants found their experience of this clinical trial. Ninety-one (91%) respondents said they found participating in a clinical trial to be a good experience. One person (1%) said they found it a bad experience while 6 (6%) respondents found the experience to be neutral.

The ONTARGET clinical trial participants were asked if they would participate in a clinical trial again if they had the opportunity to do so. Sixty-five (65%) respondents said they would participate again, 15 (15%) said no while 20 (20%) respondents were not sure if they would participate in a clinical trial again. Four (4%) of the respondents who indicated they would not participate again cited their age as the reason they would not participate again. Eighty-five (84.16%) respondents said they would recommend participating in a clinical trial to a friend or relative if they had an illness. Four (3.96%) respondents said they would not recommend it, while 12 (11.88%) were unsure. When the respondents were asked if they would give consent for a child to participate in a clinical trial if they had an illness the response was mixed. Forty-three (46.74%) respondents indicated they would give consent, 11 (11.96%) said they would not and 38 (34.03%) were unsure. Sixty-four (72.73%) respondents, said they thought their experience of clinical research could not be improved, while 24 (27.27%) respondents said they thought it could be improved. In response to whether or not they had ever heard of an ethics committee or the local medicines regulatory authority (Irish Medicines Board) 60 (62%) and 73 (75%) respondents said they had heard of an Ethics Committee and the Irish Medicines Board respectively.

Finally the respondents were asked if they felt they received better healthcare because they took part in a clinical trial. In answer to this question, 85 (87.63%) respondents, indicated that they believed they did receive better healthcare because of having participated in a clinical trial, while 12 (12.37%) participants did not believe they received better healthcare (Table 4).

Discussion
In an effort to understand the reasons behind patients' participation in trials, we conducted a survey of recent clinical trial participants attitudes to see if areas for improvement in the conduct of trials could be identified. Singh et al's Formulation of Health Research Protocol A Step by Step Description Everyone would like to know about questionnaires but were afraid to ask 5 were consulted in the generation of the survey questionnaire.

The results of this questionnaire suggest that patients are motivated by several factors to enter a clinical trial (i.e. close monitoring of illness, to help others, because their doctor suggested it and to get access to study treatments; Table 2). Generally, the respondents’ view of their experience of participating in a clinical trial was positive, with 81 (91%) participants indicating that it was a good experience (Table 3) and 85 (84.16%) participants indicating they would recommend participation to a friend or relative. Sixty-five (65%) respondents said they would participate in a clinical trial again. Prior research has found that patient awareness and understanding of clinical trials is a factor in whether or not a patient will participate. Our research may correlate with that finding. Mosconi et al 6 reported that 980 (49%) of Italian health consumers surveyed indicated they would participate in a therapeutic randomised clinical trial. While Jenkinson et al 7 found in surveying patients with asthma or cancer that 518 (55.6%) of respondents said they would definitely or probably take part in a trial. Mosconi et al 6 reported that they would definitely or probably take part in a clinical trial. Our population consisted solely of people who had participated in a clinical trial. Our higher rate of hypothetical participation in a future clinical trial may be because having already participated in a clinical trial these respondents have an awareness and better understanding of clinical trials.

With regard to how the experience of clinical trial participation could be improved, only those respondents (24 (27.27%)) who indicated that they thought the experience could be improved were asked to comment as to how it could be improved. A free text box for the respondents comments was used so as not to influence their response. The general trend of the comments section is that there should be more information, explanation and contact given to the participants. The respondents thought that they should be given more information in ‘layman’s terms’ on why procedures are being carried out, and that more frequent monitoring of them should take place and that contact between the clinical trial participants would improve their experience. Finally, they indicated that they should be recognised for their participation, maybe in the form of a certificate of participation. In keeping with the suggestions of greater transparency, more information and recognition of their participation Sood et al 5 found that 364 (91%) of patients surveyed wanted to be informed about research findings and if not 272 (68%) patients said they would not participate in future clinical trials.

The patients in ONTARGET received reasonable travel expenses (e.g. transport or hospital parking costs) but did not receive any other compensation for taking part. In the Irish healthcare environment, the treatments evaluated in ONTARGET could have been made available to patients outside of a clinical trial setting. It is considered unlikely that they were motivated to participate in this trial for financial reasons or to gain access to new treatments.

This survey is limited by the fact that it was done in a specific subset of trial participants (i.e. a long-term, cardiovascular outcomes trial). However, Ross et al 4 in their systemic review of barriers to participation in randomised controlled trials, found that illness severity, age or level of education did not consistently influence...
likelihood to participate. While it is encouraging to see that a high proportion indicated that their experience of clinical trial participation was a positive one, it is very important to use the feedback from this questionnaire to make the clinical trial participants’ experience a better one in the future. Some of the feedback in this questionnaire may be particular to long-term clinical trials but the general suggestions of greater transparency, more information in ‘layman’s’ terms and recognition of their participation are applicable to all clinical trials. It is incumbent upon all of us involved in clinical research to endeavour to make clinical trial participants experience a positive one. Each and every person who has ever received a pharmaceutical medicine is indebted to the clinical trial participants who enabled the medicine to be available for prescribing.

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