

12.3_Intro

Report A

Perceptions of clinical trials by ethnic-minority and non-ethnic-minority patients

Introduction

There has been much debate about the levels of participation by ethnic minorities in clinical trials. It is important that ethnic minorities are adequately represented; otherwise trial results may not provide a true picture of the effectiveness and safety of drugs across the whole population.

This report will describe a survey undertaken to examine differences in the perception of clinical trials between individuals from ethnic minorities and non-ethnic-minority individuals. Recommendations will be made on how recruitment of volunteers from ethnic minorities can be improved.

Method

A written questionnaire was designed to measure how ethnic minorities perceived the safety and likely societal benefits of clinical trials compared with their non-ethnic-minority counterparts. Six hundred questionnaires were sent to a random sample of patients selected from each of the two subject groups. Two hundred and fifty were returned. In addition, twenty-five patients from ethnic minorities were interviewed in GP surgeries. Over 65% of the sample were women.

Findings

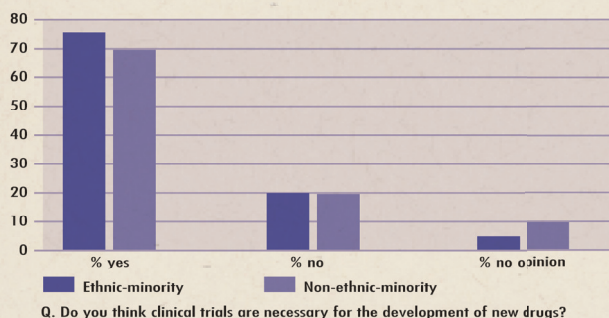


Figure 1: Perception of need for clinical trials

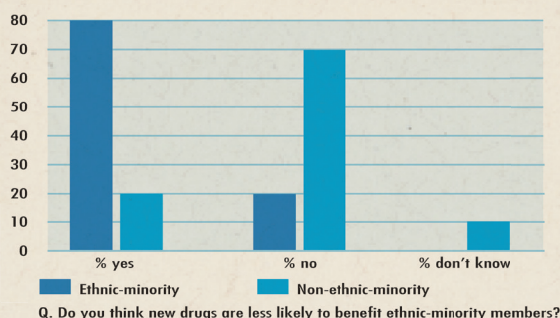


Figure 2: Perception of benefits of new drugs to ethnic minorities

Firstly, a minority (30%) of ethnic-minority respondents stated that they were unlikely to agree to take part in a clinical trial if asked. Moreover, the majority (60%) said they were likely to agree; only a small proportion (10%) were unsure. The results

from the non-ethnic-minority sample were similar. A significant majority (70%) of non-ethnic-minority respondents indicated that they were likely to participate, while a minority (30%) felt it was unlikely they would want to be involved.

The survey showed that in relation to understanding the need for clinical trials, the results were broadly similar between the two groups. Firstly, an overwhelming majority of ethnic-minority respondents (75%) felt that clinical trials were necessary for the development of new drugs, compared with 70% of non-ethnic-minority respondents. Secondly, a significant minority of both ethnic-minority and non-ethnic-minority respondents (20%) felt that clinical trials were not necessary. Finally, a very small minority of ethnic-minority respondents (5%) had no opinion, along with a larger minority (10%) of non-ethnic-minority respondents.

The question of whether new drugs were less likely to benefit members of ethnic minorities showed a very interesting difference between the two groups. Firstly, an overwhelming majority of ethnic-minority respondents (80%) said they agreed with the statement, whereas only a significant minority of non-ethnic-minority respondents (20%) agreed. Moreover, a significant majority of non-ethnic-minority respondents (70%) disagreed with the statement, along with the remaining 20% of ethnic-minority respondents. A small number of non-ethnic-minority respondents (10%) had no opinion.

Ethnicity was mixed, with a larger proportion of patients of Asian origin (India 22% and Pakistan 31%) than patients of black origin (28%). There were also considerable differences in the level of understanding of English and literacy, as indicated by the information provided about who completed each questionnaire.

Discussion

It is clear from this research that there are many similarities in the perceptions of ethnic-minority and non-ethnic-minority patients regarding clinical trials. However, there are also some major differences. The most significant was whether respondents believed new drugs were less likely to benefit members of ethnic minorities. The return rate was exceptionally high, at over 40%, which can give us reasonable confidence in the validity of our results.

Conclusion

In conclusion, it is clear that while there are significant differences in perception of clinical trials between individuals from ethnic minorities and non-ethnic-minority respondents, these do not appear to influence willingness to take part in trials. Ethnic-minority patients were more aware of the need for clinical trials, but doubted that the new drugs would benefit their community equally. It is important that this perception is challenged and evidence put forward that this is not the case. A considerable number of those interviewed were unable to read English and would therefore require translators. Unless these recommendations are put into practice in the near future, ethnic minorities will continue to be underrepresented in clinical trials. However, there is a good chance that if implemented, the suggested changes will produce a favourable result.

12.3_Intro Report B

Literature search to determine issues affecting ethnic-minority participation in clinical trials

Introduction

Clinical trials are an essential part of the development process of new drugs. However, members of ethnic minorities are often underrepresented in trials, and it is important to understand why this is the case. Identifying the issues that cause this underrepresentation will make it possible to address them in practice and to increase the number of ethnic minorities represented in trials. This report describes a literature search which provides a summary of the issues in this area; suggestions will be made for addressing these issues in practice.

Method

In order to find out what the main issues surrounding the level of participation by ethnic minorities in clinical trials are, a literature search was undertaken using the PubMed database and Google Scholar. The search terms which were used were *ethnic minority*, *participate* and *clinical trial*.

Findings

Six main issues relevant to the recruitment of ethnic-minority participants to clinical trials were identified in the literature search. The first of these was the issue of disclosure of the illness to the patient. In many cultures, it is common to provide the family with the diagnosis rather than the patient. While this is against the principles of patient autonomy, in situations where the patient is unable to speak English and family members have to act as interpreters, it is difficult to be sure how much the patient knows. This links to the second issue, which is poor levels of literacy, even in the mother tongue, which adds to the difficulty of communicating with the patient. A third issue, linked to the first, is a cultural preference for making decisions as a family, rather than allowing the individual to decide. This can lead to confusion and mixed messages and links to the fourth issue, lack of perceived relevance. Patients

and their families are not clear what the benefits of participation are, to them or their patient group, and are often unsure about what taking part can mean. The fifth issue is lack of familiarity with research methodology and randomization. This means that these patients are less likely to be able to evaluate risk in relation to the trial. The final issue is the belief by many of these patients that new drugs are less likely to benefit ethnic minorities than the non-ethnic-minority population.

Discussion

It is clear that there are a number of ethical principles which need to be considered in relation to these issues. Perhaps the most important of these is autonomy. Many of these patients are unable to speak English very well and have low literacy levels, even in their own language. The family-based decision-making process is also a barrier, particularly as the family may not want the prognosis to be revealed to the patient. Other issues relate to the principle of justice, where patients do not perceive equal benefits to their ethnic group compared to the non-ethnic-minority population.

Conclusion

To conclude, it appears that while many of the problems in recruiting ethnic-minority participants also apply to non-ethnic-minority communities, these problems are representative of broader issues relating to how health services interact with minority groups. For example, a considerable number of potential participants from all ethnic groups may be unable to read well in English; nevertheless, the impact on ethnic-minority groups is greater because of other contributing factors. The evidence suggests that cultural issues should be taken into account when obtaining consent from ethnic-minority patients to participate in clinical trials. More emphasis should be put on face-to-face discussion. Where necessary, a qualified translator should be used, and the family should be encouraged to ask questions. The underrepresentation of ethnic minorities in clinical trials is likely to continue if the implementation of these recommendations is delayed. Speedy implementation should see the erosion of many of the identified barriers.