

This study is part of a senior training project from the Center for Overview, Meta-analysis, and Evidence-based medicine Training (COMET) (http://it.geocities.com/comet_milano/Home.htm). We thank the authors of the systematic reviews for their help.

Contributors: See bmj.com.

Funding: None.

Competing interests: None declared.

Ethical approval: Not required.

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(Accepted 14 November 2005)

doi 10.1136/bmj.38693.516782.7C

Receiving a summary of the results of a trial: qualitative study of participants' views

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Editorial by MacNeil and Fernandez

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BMJ 2006;332:206-9

Abstract

Objective To explore trial participants' responses to receiving a summary of the results of a trial in pregnancy.

Design Qualitative study with semistructured interviews.

Participants 20 women who had when pregnant participated in the ORACLE trial of antibiotics for preterm labour and preterm rupture of the membranes and requested a copy of the trial results.

Results Less than a fifth of women who participated in the ORACLE trial indicated that they wished to receive the trial results. Reactions to the leaflet summarising the trial results were generally positive or neutral, although some women had difficulty in understanding the leaflet, and there was evidence of possible negative implications for women who had adverse outcomes. Women requested the results because they were interested in being able to complete their own personal narrative. They wished to know to which arm of the trial they had been allocated and the implications for their own pregnancy, and they were disappointed with receiving a generic summary. Women's accounts indicated some confusion about the trial findings.

Conclusions Recommendations that research participants be routinely provided with the results of studies have been made without the benefit of research to show the consequences of doing this or how it should best be managed. Caution is needed, as

is more evaluation of how feedback of results should be handled, and assessment of the risks, benefits, and costs.

Introduction

The idea that research participants should be given the results of studies in which they have participated is one that has gained ground. It has been promoted as an element of responsible ethical research practice,¹ and as a participant's right.²⁻⁵ Despite these positions on the desirability of feeding back results to study participants, little research has been done into the outcomes and implications of providing such feedback or into how it should best be managed.⁶ We explored the views of women who received a leaflet summarising the findings of the trial in pregnancy in which they had participated.

Methods

We conducted a qualitative study based on in-depth interviews with women who had participated in the United Kingdom in ORACLE, a large randomised trial, and who had requested the results of the trial. All participants provided informed consent.

ORACLE was a double blind randomised controlled trial of antibiotics in pregnancy, designed to test the



This is the abridged version of an article that was posted on bmj.com on 9 January 2006: <http://bmj.com/cgi/doi/10.1136/bmj.38675.677963.3A>

hypothesis that treatment with broad spectrum antibiotics prolongs labour and reduces neonatal mortality and morbidity for women who are less than 37 weeks pregnant, and who are either in preterm labour or have prelabour rupture of the membranes.^{7,8} The trial showed that for women in spontaneous preterm labour, antibiotics did not prolong pregnancy nor improve the health and survival of babies. By contrast, for women with preterm prelabour rupture of the membranes, erythromycin prolonged pregnancy and was associated with improved outcomes for babies. Augmentin was associated with a higher incidence of the very rare but potentially serious condition of necrotising enterocolitis, a gastrointestinal disease that causes destruction of the bowel in babies.

Women could request a copy of the results of the trial by either of two methods. Firstly, all ORACLE participants in the UK got a "thank you" card, which asked if they wanted to receive the results. Secondly, the 3074 ORACLE participants from 55 maternity units who were included in a survey about their understanding of the trial⁹ were given a second opportunity to request a copy of the trial results. When the trial was complete, all women who had requested the results were asked to confirm that they still wished to receive them.

The results leaflet comprised a two page summary of the ORACLE findings, written in close collaboration with a consumer representative from the trial steering committee. The leaflet explained that the results might remind participants of a difficult time, and offered the opportunity to contact the ORACLE team in case of any questions. A telephone support helpline was set up by the Medical Research Council (MRC).

All women who had requested the results in the Trent region of the UK received a letter asking if they wished to participate in a face to face interview about their reactions to the results leaflet. Women who agreed to an interview were interviewed at home by KCW, using a flexible interview prompt guide, developed after literature review and discussions in the project team. KCW transcribed interviews verbatim. We employed a systematic and iterative method of analysis based on the constant comparative method.¹⁰ (See bmj.com for full details of the analytic approach.)

Results

8941 women were offered the opportunity to request the trial results, and one third of these were given two opportunities, but only 1803 (20% of all participants) requested this information. Of these, 1524 (17% of the original participants) subsequently confirmed that they still wished to receive the results. The MRC helpline had no calls from any women who had received the trial results, but the ORACLE office received a small number of requests from women to be unblinded.

In the Trent region, 193 women requested the results, and all received a letter inviting them to participate in an interview about the results leaflet. We conducted interviews with 20 of the 22 women who agreed to be interviewed. Although we were unable to conduct purposive sampling in these circumstances, the sample was socially (although not ethnically) diverse. Most of the categories of the analysis were highly saturated, but without further theoretical

sampling it was not possible to determine whether theoretical saturation was reached.

Women's accounts showed that they were between 22 and 33 weeks pregnant at the time they were recruited into the ORACLE trial. Of these women, 10 reported ruptured membranes. None had babies who had died or had necrotising enterocolitis after participating in ORACLE.

Getting the results

All of the women who participated in this qualitative study had elected to receive the results of the trial. For most (15) women, their interest in the results included, but was not necessarily limited to, discovering which arm of the trial they had been allocated to. This was strongly linked to interest in whether the allocation had had any impact on their own pregnancy. Other issues of interest to women included whether antibiotics had been successful in preventing preterm birth or infection in babies, how the drugs worked in preventing preterm birth, implications for treatment of pregnant women, whether the drugs had caused harm, and whether participating had been worthwhile.

Of the participants who spoke about the method of sharing the results with participants, most found receiving a results leaflet through the mail satisfactory or preferable to personal contact. Written material was seen as having the advantage of being available to study at length and in private.

Just over half of the women reported reading the leaflet with care and half reported reading the leaflet more than once, but the pressures on the time of new parents were prominent in participants' accounts. However, several women said that bereaved parents, or those whose child had health problems, might find a leaflet problematic. Two women, including a participant whose child had bowel problems, indicated that they would have preferred a telephone call or a personal visit to explain the results, rather than a leaflet.

Positive reactions to the results leaflet

Most of the comments on the content and format of the leaflet were positive. Half of the women found the leaflet clear. For most women the leaflet had a positive impact or little impact. Half expressed feelings of pleasure on receiving the leaflet, particularly at what they saw as the success of the trial, or felt that taking part had been worthwhile.

Negative reactions

Several participants pointed to particular "bits" of the leaflet that were difficult to understand, and three women found the leaflet difficult to understand in general.

Participant 20: "I don't think I did [understand it] to be honest, I think I was a bit bewildered by what it was all about kind of thing. It was a bit mumble jumble, too, oh this sounds awful, doctor-ified, you know, like not brought down to our way of thinking. If it had just been in like little boxes it would have, I'd have digested it better, I think's the best way of putting it."

One negative consequence of receiving the results was that for some women (five) it revived memories of a difficult time, or had the potential to do so if the outcome of the pregnancy had been different (two).

The most common reason for disappointment on receiving the results, experienced by most (15) women, was the lack of personalised information. Participants wanted to know the arm of the trial to which they had been allocated and the possible consequences of this:

Participant 3: "Yes, because when I was sent that I thought, I didn't realise it was just the global study results, I thought that the results would include your own personal results because there were, there was correspondence obviously to individuals."

Many participants attempted to interpret the results in terms of their own pregnancy. The impact of receiving the results for Participant 10, whose child had bowel problems, was considerable, provoking distress that resolved only when she established that she had been taking the placebo.

Participant 10: "Cos I was so worried, I thought well if I'd been taking those tablets that said in the study that they caused bowel problems in some babies maybe that's what was wrong ... I felt panic because I didn't know, I thought, soon as I read the bit about the bowels I thought, 'My God, I bet that's what's caused [child] to be like he is.' ... and you just need to turn to somebody then to find out, and then I'm thinking, 'What tablets did I take?' You know, it was all racing round in me mind again, did I take real ones? ... Then I got on to me doctors and got on to 'em a lot, and then eventually they wrote the ORACLE study, and they got me the results back saying that they was the false ones. So I was relieved in a way and I thought, 'Well I know that it ain't those that have caused it.'"

Others were disappointed that the trial had not revealed the causes of preterm birth and treatments to prevent it.

Knowledge of the results

Most participants showed at least some knowledge of the study results, although we saw evidence of considerable confusion. Thirteen women knew that antibiotics or one of the antibiotics increased the length of pregnancies, but only five showed an understanding that this was limited to those pregnancies where the membranes had ruptured.

Participant 4: "No, well ... it went into what the trial was about and things like that, but it didn't really give you any results or any concrete evidence, information—the trial worked; the trial didn't work; it was a success."

Only two participants made reference to the risk associated with taking one of the antibiotics in pregnancy. (See bmj.com for additional quotations.)

Discussion

Providing results to participants in research studies is not straightforward; it constitutes an intervention in its own right and requires more rigorous evaluation than it has previously received. These are interesting findings, as provision of results has been encouraged based on bioethical arguments about the need for respect for autonomy and other ethical principles,^{1 11} and more recently on the grounds that it is an expression of accountability to research participants.¹²

Providing summary leaflets

In contrast with some small studies that have identified much interest in receiving research findings among participants,^{13–15} we found that a substantial proportion of women who participated in the ORACLE trial (over

What is already known on this topic

It is currently recommended that research participants be provided with results of studies in which they participate

Little is known about best practice in provision of results or about the consequences of providing results

What this study adds

Women who participated in a trial in pregnancy were primarily interested in being able to complete their own personal narrative rather than receiving a summary of study findings, and showed evidence of some confusion in relation to the trial results

Providing results of trials to trial participants is not straightforward and constitutes an intervention in its own right

More evidence is needed about appropriate methods for disseminating trial results to participants and the impact of these

80%) did not indicate that they wished to receive the results. The motivation for many women in seeking results was their need to interpret participation in the research within their own personal narrative, and they therefore wished to have individualised reports of the intervention they received and the outcomes of this. In some cases, women wanted to know the unknowable—whether a particular intervention led directly to a particular outcome for them. Providing summary leaflets does not address these needs, and such needs may themselves point to a basic mismatch between the understandings of trial designers and trial participants about the purposes and products of trials. More generally, as others have found,¹³ leaflets are a satisfactory method of communication for many participants, but they may be less suitable for those who have had adverse outcomes. These findings support earlier suggestions that only those who request research findings should be given them,¹⁶ but more generally they raise questions about how the process can best be managed for those who do wish to receive results.

Limitations of the study

It is possible that different methods—such as ticking a box at the time of recruitment—might have resulted in a higher proportion of women requesting the results, and it needs to be identified how and when opportunities to request results should be provided. The women who took part in this qualitative study were a select group who had agreed to take part in the ORACLE study, requested the results, agreed to be interviewed, and lived in a single (albeit extensive) English region. These women's accounts offer insight into the views and experiences of those who were quite persistent in their wish to receive the trial results and offer their reactions; future research should attempt to access other groups. The babies of all of the participants survived, and some participants implied they may have felt differently if the outcome had been different.

Should individual trial results be provided?

The question of whether research participants should routinely be provided with individualised data is an important one that requires further exploration, particularly given the strength of feeling expressed in our study. In the area of genetic epidemiology, current international guidance¹⁷ says that, in general, participants should not be provided with information on their genotype. This is because the clinical importance of the results will be unclear and could be used in unintended ways that might result in risks for the participants or their kin and could confuse the role of the researcher with the role of the doctor; this is supported by qualitative work in the field.¹⁸

Implications for future research

It is important that evaluation of whether individualised results should be provided is holistic and is not derailed by arguments that failure to do so is simply a form of paternalism. Best practice needs to be identified, rather than assuming that providing research results to participants is straightforward. Better informed and more sophisticated debate, which acknowledges the contribution of social science research rather than accepting uncritically the legitimacy of bioethical pronouncements,¹⁹ is required.

Acknowledgements: We thank David Taylor, Richard Lilford, Hazel Thornton, and Gill Gyte for valuable comments on earlier drafts. We also thank Claire Snowden for initial input into the study design.

Contributors: See bmj.com.

Funding: This study was funded by the UK Medical Research Council as part of the MRC ORACLE trial.

Competing interests: SK was an investigator on the MRC ORACLE trial.

Ethical approval: North West Multicentre Research Ethics Committee.

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(Accepted 8 November 2005)

doi 10.1136/bmj.38675.677963.3A

Women's experiences of, and preferences for, services after rape in South Africa: interview study

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Abstract

Objectives To describe aspects of delivery of health services after rape, including trade-offs, that would most influence choice of service, and to compare views of patients who had used such services with views of members of the community who may be future users or may have experienced barriers to service use.

Design Discrete choice analysis of stated preferences with interviews. Attributes included travel time to the service, availability of HIV prophylaxis, number of returns to the hospital, medical examination, and counselling skills and attitude of the provider.

Setting One rural and one urban site in South Africa.

Participants 319 women: 155 who had been raped and four carers recruited through health facilities and 160 comparable women recruited from the community. Of these, 156 were from an urban site and 163 from a rural site.

Main outcome measures Strength of preferences over a range of attributes through the estimation of a benefit function through random effects probit modelling.

Results Factors such as the availability of prophylactic treatment for HIV infection and having a sensitive healthcare provider who could provide counselling are more important in women's decisions to seek care after rape than the travel time necessary to access those services.

Conclusion Our findings support the need for holistic rape services.

Introduction

Women who have been raped have specific health needs: the prevention of pregnancy, HIV, and other

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BMJ 2006;332:209-12



This is the abridged version of an article that was posted on bmj.com on 5 December 2005: <http://bmj.com/cgi/doi/10.1136/bmj.38664.482060.55>