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Research

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

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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] or as a participant's right: the then editor of the *BMJ* in 1995 declared, together with a former study participant, that one thing that may be important for achieving the full cooperation of patients in designing, conducting, reporting, and implementing the results of research may be to ensure that they are the first people to hear the results.[2] A similar point was made in a submission to the UK Select Committee on Science and Technology,[3] and the second edition of the Department of Health's research governance framework recommends that findings from research work be disseminated promptly and fed back as appropriate to participants.[4] The UK National Childbirth Trust and the Association for Improvements in Maternity Services, in their charter for ethical research in maternity care, state that participants in studies in pregnancy should have the right to see the results.[5]

Despite these strong 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. Interviews aimed to explore women's views about receiving a leaflet summarising the results of the trial. All participants provided informed consent.

ORACLE was a double blind randomised controlled trial of antibiotics in pregnancy, funded by the UK Medical Research Council.[7 8] It was designed to test the 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. ORACLE used a 2×2 factorial design, with four treatment possibilities: augmentin 375 mg, erythromycin 250 mg, either antibiotic with placebo, or both placebos. During the period of the trial (July 1994-May 2000), 11 154 women were randomised to ORACLE from 161 maternity units worldwide, including 135 units in the UK. 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 shortly after participating in the trial, 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 trial[9] 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. It

was sent out at the same time as the results were published in the scientific journals, and it was therefore not possible to conduct extensive piloting. 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, who maintained a diary to record contextual details and her reflections on the research process. She used an interview prompt guide, developed after literature review and discussions in the project team, to structure the interviews, but she used this flexibly in response to the ways in which the participants wanted to direct the interview. KCW transcribed interviews verbatim. We employed a systematic and iterative method of analysis based on the constant comparative method.[10] Initially, "open codes" were generated from the data representing the importance of sections of text. We then grouped these open codes incrementally into organising categories, which we modified and checked constantly in order to develop a coding frame with explicit specifications with adequate "fit" with the data. CJ maintained a reflexive audit trail of the development of the framework and its categories. CJ programmed the coding frame into QSR N5 software, and used this to process the dataset systematically. MDW independently checked the assignment of data to categories.

Results

All of the 8941 women who were recruited to ORACLE in the UK 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. The analysis showed that 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. No participants 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 worth while.

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.

Participant 14: "I was fine with the letter. You can, because ... you can go over and over and over it, like a phone call you can't always remember what was actually said and things like that, and, you know, and even if somebody comes to your door, if you've got a letter and you're on your own you can take it how you want to take it."

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 Participant 10, 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.

Participant 16: "I suppose some of the letters and some of the questions would have been harder for me to have dealt with and receive ... if I'd have lost my son ... sometimes I've read things and thought, 'Oh dear, if I'd have lost me baby that would have been hard to accept.' And had I have lost my baby then ... no I didn't want the results in a letter, I'd want somebody to come and talk to me."

Participant 10: "Yeah, I think that, knowing that there's women out there who's probably got babies with, like, who have struggled since being on the ORACLE study, maybe not linked to the study at all, but there are women who are probably worried with concerns like me, they'd obviously like someone to turn to rather than just read a piece of paper and feel isolated."

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.

Participant 1: "Yeah it was written out very clear; it was very easy to understand, and they asked us if, you know, we had any questions, any worries or anything, you know, to get in touch with them and they thanked us for taking part and that it could be, you know, it could be upsetting, you know, to think back to it all. It was really, really done, wrote out well."

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 worth while.

Participant 11: "And that was how I felt, more afterwards I suppose than at the time I was glad that I'd done it, but afterwards, and especially after the leaflet, I felt that I'd perhaps helped some other mums."

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).

Participant 2: "And obviously it does bring back memories of a time when, well, things were tough I suppose."

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 pre-term birth and treatments to prevent it.

Participant 14: "Yeah it told me what I wanted to know. I just, I think my expectations were a little high, you know, I was thinking that they'd find a cure, you know, they'd find a cure and ... no more mothers would actually go into premature labour ... I think with the medical like institution you think that the, they're magic sort of thing, you know, and you think that they can cure everything and, you know. So it was like a little disappointing cos I expected it just to be a little bit, 'We can cure premature labour and hurrah!'"

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.'"

Participant 16: "Yeah, when I got the, when I got the letter saying that, you know, that it had proved that, through research that giving the antibiotics did help it wasn't a shock. It was like well I believed it anyway because of how it happened to me."

Interviewer: "Had your waters broken?"

Participant 16: "No, no, at no stage had me waters broken. No, it were just me uterus was contracting."

Only two participants made reference to the risk associated with taking one of the antibiotics in pregnancy.

Participant 2: "I think I was quite surprised to find in the results that there was an area of risk, wasn't there? For preterm, that a couple of babies actually ... they did actually develop something quite rare, didn't they? And I think some of them have obviously died as a result of that, although they said most of them did come through it sounds like that there've been possibly some deaths linked immediately, you know, directly to it."

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 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. Even if leaflets have consumer involvement in their preparation, potential remains for unpredictable forms of misunderstanding, anxiety, and distress, and for leaflets to reactivate memories of traumatic periods in people's lives, especially as results may be available only some years after the original participation. 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. Participant 10 came closest to an unfavourable outcome, and for her, the impact of results was considerable.

It could be argued that our study might have produced different findings, with more positive reaction from participants, if the results leaflet had been better designed or the content had been improved. Although there is little evidence of a direct linear

relation between characteristics of leaflets and particular outcomes,[17 18] it is possible that greater involvement of those who had participated in the trial in the design of the leaflet, and more extensive piloting, might have been helpful. This would require further evaluation in future studies and will be an important focus of research.[19]

Should individual trial results be provided?

The main area of disappointment concerns the failure to provide individualised results that would enable women to complete a personal narrative of their pregnancy. 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. Research activity and debate around the issue of treatment debriefing are increasing,[20] although there are as yet no signs of an emerging consensus on best practice. In the area of genetic epidemiology, current international guidance[21] 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. Qualitative work has shown that feedback of individualised data in genetic epidemiology studies is indeed fraught with difficulties and has concluded that, unless clear and specific reasons exist, individual feedback should not be offered.[22]

Implications for future research

The appropriateness of this kind of cautious approach requires careful evaluation. It is important that such evaluation is holistic and is not derailed by arguments that failure to provide individualised results is simply a form of paternalism; it could even be argued that the current insistence that results should be provided is also a form of paternalism that rests on third parties determining what is in trial participants' best interests without asking them. Best practice needs to be identified, rather than assuming that providing research results to participants is straightforward. Areas that require further investigation in particular include further assessment of the risks and benefits of provision of results, especially for people in the least effective arms of trials or those who have had adverse outcomes; determination of patients' and investigators' views and preferences on how and when results should be fed back and in what form; identification of what support systems should be in place; and evaluation of the financial and opportunity costs associated with providing results.[23] Better informed and more sophisticated debate, which acknowledges the contribution of social science research rather than accepting uncritically the legitimacy of bioethical pronouncements,[24] is required.

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1 Fernandez CV, Kodish E, Weijer C. Informing study participants of research results: an ethical imperative. *IRB Ethics Hum Res* 2003;25:12-9.

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

2 Goodare H, Smith R. The rights of patients in research. *BMJ* 1995;310:1277-8.
3 United Kingdom Parliament. *Draft guidelines for ethical research with patients.* www.publications.parliament.uk/pa/cm199900/cmselect/cmsctech/332/0062116.htm (accessed 19 Nov 2005).
4 Department of Health. *Research governance framework for health and social care.* 2nd ed. London: DoH, 2005.
5 Association for Improvements in Maternity Care (AIMS), National Childbirth Trust. *A charter for ethical research in maternity care.* London: AIMS/NCT, 1997.
6 Schulz CJ, Riddle MP, Valdimirsdottir HB, Abramson DH, Sklar CA. Impact on survivors of retinoblastoma when informed of study results on risk of second cancer. *Med Pediatr Oncol* 2003;41:36-43.
7 Kenyon SL, Taylor DJ, Tarnow-Mordi W, ORACLE Collaborative Group. Broad-spectrum antibiotics for preterm, prelabour rupture of fetal membranes: the ORACLE I randomised trial. *Lancet* 2001;357:979-88.
8 Kenyon SL, Taylor DJ, Tarnow-Mordi W, ORACLE Collaborative Group. Broad-spectrum antibiotics for spontaneous preterm labour: the ORACLE II randomised trial. *Lancet* 2001;357:989-94.
9 Kenyon S, Dixon-Woods M. What do they know?: a content analysis of women's perceptions of trial information. *BJOG* 2004;111:1341-5.
10 Glaser BG, Strauss AL. *The discovery of grounded theory: strategies for qualitative research.* Chicago: Aldine, 1967.
11 Partridge AH, Winder EP. Informing clinical trial participants about study results. *JAMA* 2002;288:363-5.
12 Zlotnik Shaul RD, Reid L, Essue B, Gibson J, Marzinotto V, Daneman D. Dissemination to research subjects: operationalizing investigator accountability. *Account Res* 2005;12:1-16.
13 Marshall S. Participants should be given feedback about the trial. *BMJ* 1996;312:186.
14 Partridge AH, Burstein HJ, Gelman RS, Marcom PK, Winer EP. Do patients participating in clinical trials want to know study results? *J Natl Cancer Inst* 2003;95:491-2.
15 Partridge AH, Wong JS, Knudsen K, Gelman R, Sampson E, Gadd M, et al. Offering participants results of a clinical trial: sharing results of a negative study. *Lancet* 2005;365:963-4.
16 Snowdon C, Garcia J, Elbourne D. Reactions of participants to the results of a randomised controlled trial: exploratory study. *BMJ* 1998;317:21-6.
17 Dixon-Woods M. Writing wrongs? An analysis of published discourses about the use of patient information leaflets. *Soc Sci Med* 2001;52:1417-32.
18 Robinson EJ, Kerr CE, Stevens AJ, Lilford RJ, Braunholtz DA, Edwards SJ, et al. Lay public's understanding of equipoise and randomisation in randomised controlled trials. *Health Technol Assess* 2005;9:1-192.
19 Thornton H, Edwards A, Elwyn G. Evolving the multiple roles of 'patients' in health-care research: reflections after involvement in a trial of shared decision-making. *Health Expectations* 2003;6:189-197.
20 Di Blasi Z, Crawford F, Bradley C, Kleijnen J. Reactions to treatment debriefing among the participants of a placebo-controlled trial. *BMC Health Serv Res* 2005;5:30.
21 Beskow LM, Burke W, Merz JF, Barr PA, Terry S, Penchaszadeh VB, et al. Informed consent for population-based research involving genetics *JAMA* 2001;286:2315-21.
22 Richards MPM, Ponder M, Pharoah P, Everest S, Mackay J. Issues of consent and feedback in a genetic epidemiological study of women with breast cancer. *J Med Ethics* 2003;29:93-6.
23 Fernandez CV, Skedgel C, Weijer C. Considerations and costs of disclosing study findings to research participants. *CMAJ* 2004;170:1417-9.
24 Lopez J. How sociology can save bioethics ... maybe. *Sociol Health Illn* 2004;26:875-96.

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