

# **Feedback of trial results to participants: A literature review and stakeholder survey**

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## **Executive Summary**

The policy imperative to increase recruitment to cancer clinical trials is reflected in a growing body of research into accrual into trials. However, there are a number of gaps in the research base relating to the closure of clinical trials and feedback of results to participants.

This report presents the findings from a piece of work that was designed to review the current literature relating to trial closure practice, including ethical principles, clinician and patient attitudes, drawing on documented details of trial closure procedures; and to survey both clinicians and patients about their views of and attitudes towards the feedback of trial results. This was achieved by:

- (1) Undertaking a comprehensive review of the literature regarding feedback of clinical-study results to participants
- (2) Surveying the views of key individuals in the NCRI Clinical Studies Groups about feedback of results to participants
- (3) Obtaining trial participants views about the feedback of trial results to participants

## **Summary of findings**

Selection of papers and reports for inclusion in the review of the literature was based on the following eligibility criteria:

- Work describing the views, beliefs, or experiences of people relating to feedback of trial results
- Work describing interventions relating to the feedback of trial results
- Work undertaken between 1990 and the present

In all, we reviewed more than 4000 abstracts and 100 full publications, including 34 empirical studies. The major findings from the review are outlined below:

### ***Views of research participants about results feedback from the literature***

- Those not given results are overwhelmingly in favor of receiving them
- The majority of those offered results accept the offer
- Few who are given their results as a matter of course regret receiving them
- Results can cause distress to some respondents, however this does not appear to translate into regret at having received results

### ***Views of clinicians and research ethics committees from the literature***

- The majority of investigator or ethics board chairs support the idea of offering results
- In practice, investigators do not always return results to participants
- Few institutions have a formal plan for returning results
- The main barrier to the return of results was perceived to be the cost
- Other perceived barriers included:

difficulty of preparing lay summaries  
difficulty of contacting participants  
psychological impact on patients of learning results

### ***NCRI survey findings***

Following the literature review a survey questionnaire was sent to members of the 21 NCRI Clinical Studies Groups, including 15 cancer-site specific Groups and five generic Groups and the Consumer Liaison Group. Each of these groups has between 16 and 34 members (not including the Group Chair and Observers). In total, 145 surveys were returned, representing 32.5% of the target population of NCRI members (approx 446); 120 returns were from professional members of the NCRI and 25 were from consumer members. The main findings from the survey are noted below:

- Broad support exists for the provision of information and trial results
- 97% of surveyed NCRI members (n=145) indicated that participants should be offered a summary of trial results
- 96.5% of respondents agreed or strongly agreed that participants have a right to be offered trial results
- Most (90.2%) reported that they were personally willing or very willing to provide results
- The most frequently endorsed option for when to share results with participants was at the time of publication when the trial was complete
- The most frequently supported option for distributing results to participants overall was for patients to receive a letter indicating that results are available and a number to call for requesting them
- The issue of whether to offer results to the next of kin of deceased trial patients appeared to split respondents
- The most frequently reported potential benefit (48/132 sources) related to results transparency/awareness promoting trust in clinical trials
- Negative psychological impact on patients and carers was the most frequently reported potential drawback of offering/providing results
- The most frequently identified facilitator of feedback practice was introduction of the idea at the point of trial entry
- Respondents suggested that feedback of results had been rarely addressed in practice in relation to the trials that they had been involved with to date.
- Potential barriers to the feedback of trial results included, emotional distress caused by trial feedback and resource implications

### ***Patient survey findings***

Following the distribution of the NCRI survey a similar survey questionnaire was sent out to patients who had participated in a trial to establish the views of actual trial participants about feedback of trial results (see appendix 2). Questionnaires were sent to all patients over the age of 18 years who had

completed the active part of their trial treatment in a Cancer Network in the last 18 months April 07- July 08 (157 patients), 81 survey questionnaires were returned. The main findings from the survey are noted below:

- Nearly all respondents felt patients should be given results
- The majority of respondents stated that they would want to be informed of trial results even if the trial drug did not show any benefit and the results were negative
- A majority indicated that the next of kin of deceased trial participants should be offered results
- Respondents were split between providing results as the trial progressed and when the trial was complete
- The majority of respondents agreed or strongly agreed with the statement 'Most patients want to know the results of trials in which they've taken part', indicating a general perception that participants would be interested in feedback.
- Respondents wanted results to be returned by their doctor, face-to-face (selected by over half of those responding to the question) or by post. Post was deemed appropriate if the results were uncontroversial
- A majority of respondents indicated that they agreed or strongly agreed with the statement 'most patients understand the potential effects and implications of receiving trial results'.
- Most respondents agreed or strongly agreed that routinely offering trial results would increase patient trust in professionals.
- The majority of respondents noted offering results should be routine in clinical trials
- Only 8.9% of respondents indicated that they had been offered trial results for the recent trial they had been involved in

Currently, not enough is known about the impact of trial results to judge whether the provision of such information is beneficial or harmful to patients. In relating the findings to the original objectives of the review, it is clear that there is a need for further evidence to resolve important ethical and practical questions and identify best practice: the gaps in available evidence define areas for future research.

## Report recommendations

- 1) Available evidence suggests that trial patients perceive a right to receive trial results (in a format that they can understand) and most professionals/governing bodies support the idea of offering/providing results to patients. Thought needs to be given to how to mainstream the return of results to those who take part.
- 2) There is scope for stronger governance to direct investigators towards offering results (Mann 2002).
- 3) Both patients and professionals would be better served by further research into the consequences of results feedback (psychological).
- 4) There is a need for a controlled investigation of the cost implications of post-participation information provision.
- 5) Evidence is required to demonstrate the feasibility of offering/providing feedback (e.g., post-participation tracking), resource burden, and practical feasibility across various trial situations/outcomes and approaches to delivery/management and management of information
- 6) Current practice needs to consider the following:
  - a) asking patients at the start of a trial or when their trial participation is complete if they wish to receive the results of the trial (consider next of kin issues)
  - b) recording this preference in a database that supports long term tracking of patients' location and health status
  - c) alerting patients to the fact the results are available via post, web or available face to face
  - d) feedback of results needs to comprise of overall/aggregate results (with statistical details minimised) on: recruitment, outcomes and side effects) and their general implications, results summaries should be easy to read, the real world implications should be stated clearly and, irrespective of results, the importance of the trial (and by extension, the participant's involvement) should be stressed
  - e) If results are fed-back some evaluation of the impact on patients is important in contributing to knowledge development in this area.