

Feedback of abnormal research results

Ethical dilemmas: feeding back results to members of a longitudinal cohort study

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Does feedback of abnormal results affect validity during a longitudinal study?

A fundamental requirement of research is that no harm should come to the participants; however, being granted ethical approval for research does not imply that individuals will necessarily benefit from participation.

Certain ethical dilemmas become apparent only during the course of a longitudinal cohort study, such as the EarlyBird diabetes study in Plymouth, Devon.¹ In this non-intervention study, the aim is to observe children for 12 years, monitoring for early signs of insulin resistance. A substantial volume of data is gathered every 6 months on the children and their parents, relating to lifestyle and indices of metabolic health. Some clinical tests have parameters of results in a "normal range". When results fall outside the normal range, the only possible ethical response is to inform the individual, and, with their consent, their general practitioner.

However, ethical dilemmas present themselves in a number of situations. The first is where there is no recognised "normal range" for a certain age group (in this case, the paediatric population). The second is when, over the course of a year or two, an individual moves pro-

gressively through the "normal range" towards an undesirable endpoint. An example is the person whose weight is increasing, whose insulin and triglyceride levels, and perhaps blood pressure, are rising, but still remain within the upper limit of "normal". At what point does it become ethically necessary to offer health promotion and diabetes/cardiovascular disease prevention advice? Given the current time and financial constraints in clinical practice, any health professionals to whom such a child may be referred are unlikely to be concerned until results exceed the normal threshold.

An important characteristic of non-intervention, lifestyle cohort research such as the EarlyBird study is that it is "non-interventionist". The sample has been randomly selected to be representative of the population. To offer lifestyle advice to certain individuals, such as to reduce dietary sugar or saturated fat, to increase physical activity, or even to lose weight, may introduce bias and thus jeopardise the validity of the study. At this point, the only option may be for these participants to leave the study.

It is an inevitable consequence of health research on children that parents

will have a strong natural interest in their child's health, and that they will desire "feedback" from the study. However, the longitudinal element of the research implies that "results" will become meaningful only at the conclusion of the study, and it is therefore inappropriate to divulge information before this time. It is, of course, essential to inform the participants of these constraints on the feedback of results at the outset of the study, and before their consent is obtained. However, several years on, participants' needs with respect to health information may change.

In longitudinal studies, researchers need to balance the crucial need to minimise sample attrition (retain the participants) with the humane instinct to offer health advice, especially if it is requested. In the longer term, prospective, longitudinal research such as the EarlyBird study will generate results with a high level of evidence, which will inform clinicians and policy makers. That they should be allowed to proceed to collect unbiased, valid, high quality data is vital.

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