ISSUES, GUIDANCE & EVIDENCE - DECEPTION IN MEDICAL RESEARCH

This paper was developed as part of a Shared Ethical Debate Exercise involving 20 Research Ethics Committees and reviewed at a workshop attended by REC Chairs and Members on the 8th July 2009.

Deception: a trial in which subjects are deliberately kept unaware of some aspect of the study

(Distinctions)

Sham trials: in which the subject agrees to be randomly allocated to “active” treatment or a “sham” procedure)

Issue

When, if ever, is deception morally permissible in research?

When deception is deemed indispensable to the methods of a study the investigators must demonstrate to an ethical review committee that no other research method would suffice and that advances could or are likely to result from the research. Peer review will be important for this–

THE CENTRAL IMPORTANCE OF EXPERT REVIEW

Deception is not permissible in cases in which the deception itself would disguise the possibility of the subject being exposed to anything more than minimal risk and that nothing has been withheld that, if divulged, would cause a reasonable person to refuse to participate. – THE IMPORTANCE OF WIDE CONSULTATION WHEN DESIGNING THE RESEARCH

The ethical review committee should determine the consequences for the subject of being deceived, and whether and how deceived subjects should be informed of the deception upon completion of the research. Such informing, commonly called “debriefing”, ordinarily entails explaining the reasons for the deception. A subject who disapproves of having been deceived should be offered an opportunity to refuse to allow the investigator to use information thus obtained. Investigators and ethical review committees should be aware that deceiving research subjects may wrong them as well as harm them; subjects may resent not having been informed when they learn that they have participated in a study under false pretences.

In some studies there may be justification for deceiving persons other than the subjects by either withholding or disguising elements of information. Such tactics are often proposed, for example, for studies of the abuse of spouses or children. An ethical review committee must review and approve all proposals to deceive persons other than the subjects. Subjects are entitled to prompt and honest answers to their questions; the ethical review committee must determine for each study whether others who are to be deceived are similarly entitled.

Guidance
Withholding information and deception. Sometimes, to ensure the validity of research, investigators withhold certain information in the consent process. In biomedical research, this typically takes the form of withholding information about the purpose of specific procedures. For example, subjects in clinical trials are often not told the purpose of tests performed to monitor their compliance with the protocol, since if they knew their compliance was being monitored they might modify their behaviour and hence invalidate results. In most such cases, the prospective subjects are asked to consent to remain uninformed of the purpose of some procedures until the research is completed; after the conclusion of the study they are given the omitted information. In other cases, because a request for permission to withhold some information would jeopardize the validity of the research, subjects are not told that some information has been withheld until the research has been completed. Any such procedure must receive the explicit approval of the ethical review committee.

Active deception of subjects is considerably more controversial than simply withholding certain information. Lying to subjects is a tactic not commonly employed in biomedical research. Social and behavioural scientists, however, sometimes deliberately misinform subjects to study their attitudes and behaviour. For example, scientists have pretended to be patients to study the behaviour of health-care professionals and patients in their natural settings.

Declaration of Helsinki (WMA)
Silent on this issue
(Care & Protection of the Research Subject)
In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
(Benefits & Risks)
Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

ICH GCP
Silent on this issue

Royal College of Physicians 2007
Guidelines on the practice of ethics committees in medical research with human participants
If deception is practiced studies should be of no more than minimal risk, there should be no practical alternative methodology and debriefing must be explained and satisfactory

British Psychology Society: Ethical Principles for Conducting Research with Human Participants
Deception…… Failure to make full disclosure prior to obtaining informed consent requires additional safeguards to protect the welfare and dignity of the participants (see Section 4).

Section 4
1. The withholding of information or the misleading of participants is unacceptable if the participants are typically likely to object or show unease once debriefed. Where this is in any doubt, appropriate consultation must precede the investigation. Consultation is best carried out with individuals who share the social and cultural background of the participants in the research, but the advice of ethics committees or experienced and disinterested colleagues may be sufficient.
2. Intentional deception of the participants over the purpose and general nature of the investigation should be avoided whenever possible. Participants should never be deliberately misled without extremely strong scientific or medical justification. Even then there should be strict controls and the disinterested approval of independent advisors.
3. It may be impossible to study some psychological processes without withholding information about the true object of the study or deliberately misleading the participants. Before conducting such a study, the investigator has a special responsibility to
   (a) determine that alternative procedures avoiding concealment or deception are not available;
   (b) ensure that the participants are provided with sufficient information at the earliest stage; and
   (c) consult appropriately upon the way that the withholding of information or deliberate deception will be received.

5. Debriefing
1. In studies where the participants are aware that they have taken part in an investigation, when the data have been collected, the investigator should provide the participants with any necessary information to complete their understanding of the nature of the research. The investigator should discuss with the participants their experience of the research in order to monitor any unforeseen negative effects or misconceptions.
2. Debriefing does not provide a justification for unethical aspects of any investigation.
3. Some effects which may be produced by an experiment will not be negated by a verbal description following the research. Investigators have a responsibility to ensure that participants receive any necessary debriefing in the form of active intervention before they leave the research setting.

Royal College of Psychiatrists
Guidelines for Researchers and for Research Ethics Committees on Psychiatric Research Involving Human Participants
Council Report CR82
Approved by Council: June 2000
4.5 Participants should not be included without their knowledge or agreement in a study involving personal contact (see paragraph 3.3 regarding the exceptions with respect to group analyses of archived data). Ordinarily, participants must also be informed about the purposes of the research in which they are being asked to participate. There are occasional cases in which the essence of the scientific design requires a degree of deception. Such research needs to be carefully considered with regard to its ethical acceptability, but it may be acceptable if scientifically essential and if there is appropriate debriefing at the conclusion of the experiment.

Evidence

Can deceiving patients be morally acceptable?  
Sokol D British Medical Journal 2007 334 984
An article incorporating a possible flow chart by an author, exploring deceit in clinical practice

Evaluation of a stroke family care worker: results of a randomised controlled trial
A study in which information was withheld. It resulted in subsequent (heated) correspondence to the journal.

**Does HIV status influence the outcome of patients admitted to a surgical intensive care unit**

Bhagwanjee S et al 1997 British Medical Journal 314 1077

A prospective double blind study (approved by an REC) of all admissions to a surgical ICU over six months, testing all without consent for HIV to see if it positive patients had a worse prognosis. The ethics committee considered the clinical implications of the study important enough to waive patients' right to informed consent.

**Informed consent in medical research**

Doyal L British Medical Journal 1997 314 1107

Three exceptions identified to the need for informed consent, if the subject is incompetent to provide this, use of medical records (with certain provisos) and stored tissue from anonymous donors. The issue of “scientific reasons” is not raised, or explored rather superficially.

**Modified informed consent: consent to postponed information**

Boter H et al 2003 British Medical Journal 327 284

Patients' evaluation of informed consent to postponed information: cohort study

Boter H et al British Medical Journal 329 86

(The only article I could find that explored the participants' views of deception).

In the evaluation of outreach stroke care the researchers withheld information and then interviewed subjects. They argue that their research would not have provided valid results if consent had been sought. They therefore provided information at the end of the study (that one research question had not been mentioned in the information sheet or during the consent process) and sought the views of the group. 118 patients were recruited, 6 had died, so 102 contacted. The researcher could not find that trust in doctors had decreased, all but one would continue to take part in research, two had negative feelings after reading the information that some information had been withheld.

With a commentary from Angus Dawson, questioning the rigid rule that consent must always be sought in ethical research.

**Open randomised trial of prescribing strategies in managing sore throat**


An approved study in which patients were not given full information to “minimise contamination”

**Children's Understanding of their Research Rights**

Hurley JC Underwood MK 2002 Child development 73 132

A description of a study conducted in USA involving deception of children / research participants (BUT parents were informed of the deception and gave consent for this).

**Onora O’Neill 5th Reith Lecture**

"Yet deceivers do just this. They communicate in ways that others cannot share and follow, test and check, and thereby damage others' communication and action. They undermine the very trust on which communication itself depends: they free ride on others' trust and truthfulness."

This is what those who use deception in research must make every effort to avoid.

**(Sham procedures)**
Can a standardized acupuncture technique palliate disabling breathlessness?

Lewith et al 2004 Chest 125:1783 - 1790

This study evaluated a standardized acupuncture technique vs an appropriately validated placebo/control (mock transcutaneous electrical nerve stimulation [TENS]) for disabling, nonmalignant breathlessness (largely COPD). The subjects were not told of the "mock" nature of one of the treatments. Acupuncture was not superior to placebo, both had a beneficial effect. The authors discuss the role of mock TENS as a placebo control for acupuncture and give supporting references to its use.

Sham procedures and the ethics of clinical trials


The authors discuss the process of sham therapies in clinical trials and make the important distinction between sham trials and deception in research

"The authorisation beforehand by research subjects makes the difference between legitimate and unethical deception"

Sham surgery controls are mitigated trolleys


The authors describe the purpose and scientific benefit of sham trials (they quote an example: it was sham surgery trial that provided evidences that that internal mammary ligation was of no benefit for treating angina)

The ethical problems with sham surgery in clinical research

Summary

Guidance sees a place for it, with certain caveats.

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<th>Question</th>
<th>Considerations</th>
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| Is there very sound justification for the deception - Is this laid out in the scientific / peer review? | If deception is to be practiced, the REC will delve deeper  
- explanation of the purpose and justification will be crucial.  
- scientific review assumes greater importance, and the researcher would be well advised to provide this for the REC. |
| Is there any alternative design?                                          | This raises the question of “what is the role of RECs in research design”. Different approaches may be adopted  
But the researcher should be prepared to address the question  
“Is there a design that will answer the research question and does not require deception?”  
It would be worth the researcher discussing this with the chair before the REC considers the application. |
| What expertise and prior experience is available both the researchers and through the department? | This should be carefully explained and it is wise for appropriate attendance at the committee. |
| is the research more than minimal risk?                                  | If it is the REC will require some persuasion |
| The FDA (USA) defines minimal risk as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (§46.102i).  
The recent Royal College of Physicians guidance refers to this but advocates the Council of Europe’s definition  
“it would result at most in a very slight and temporary impact on the health of the person concerned” |
| Are the arrangements for subsequent explanation adequate?               | How long will the deception last: how has it been minimised?  
How, and by whom, will the debriefing be conducted?  
Is there need for access to longer term support? |
| What consultation with public and patients has been made?               | Patient participation in development and design of research is important in this area, and RECs will look carefully for this |
| Is it clear that when the study is explained the data may be removed if the subject wishes? | |