Incidental Findings and the Nature of Research Ethics

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Incidental findings

The problem:

- The researcher has information about the subject (that was unexpected at consent)
- Maybe important to the subject
- May involve harm/life changing effects
- Some subjects may not want to know

Examples: Lupus study, carrier status and early onset Alzheimer's, epidemiology research, biobanks, radiography

Method

- Theoretical, ethical considerations that are relevant then, trace through the practical consequences of these considerations
- The aim of this process is to build an account of the terrain of incidental findings and the way in which the relevant considerations might manifest themselves in practical contexts
- My conclusions attempt to lay out this terrain in a way that is of practical use

Practical recommendations

1. Be clear about the definition of an incidental finding

"An IF is a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study."

(Wolf et.al. 2008)

- Reproductive importance?
- What counts as 'in study' will be determined by what the research is about
- No obligation to look for certain things

Theoretical considerations

A. Consent and Respect for Autonomy

- Derives from the moral significance of self-governance
- Requires that individuals decide about participation and the extent of that participation (e.g. level of information)
- Does not mean that participants get to determine the research (or its processes) but they do get to decide about their involvement

Where does this get us?

1. Separateness of subject and researcher domains
   - The researcher is not beholden to the participant: participation is an offer
2. Lessons about consent
   - Transparent about the processes
   - What counts as part of the research and what does not
   - Access to data (subject to cost)

Practical recommendations

2. Ensure appropriate (participant-initiated) access to the data/findings
   - The principle of respect for autonomy entails that individuals should not be prevented from coming to know information about themselves
   - A negative right to the data/findings (obligation not to prevent access)
   - Given facts about research and within reason, this can often be facilitated

Theoretical considerations

B. Autonomy and Future Oriented Knowledge

- General right not to know (perhaps defeasible)
- Derives from the right to decide and the idea that respect for autonomy does not entail promotion of autonomy
- Deciding to allow others to decide (broad consent)

Practical recommendations

3. During the consent process, get a general indication of the subjects desire to know about incidental findings

- Using a spectrum of examples designed to test criteria (severity, treatability, certainty)
- Clearly cannot be specific
- Based on the 'right not to know'
- Results in guidance about feedback of IFs

"Would you want to know about these sorts of things (if something comes up) …"

Theoretical considerations

C. ‘Ought’ implies ‘Can’

- If I have an obligation to do X then X must be something that I can do

- Ethical dilemmas can be avoided by appropriately constructing the research
  - If a researcher is simply unable to feedback findings that researcher cannot be obliged to do so

Practical recommendations

4. Design the research to limit ethical problems with feedback of incidental findings
   i. Minimise the chance of finding things

   Choose tests which minimise the chance of 'coming across' information

   ii. Minimise the ability to feedback

   Where possible break links to individuals : organise the research as far as possible to prevent the possibility of feedback

An initial concern

- The limits of "ought' implies 'can"
  - Something looks wrong about simply constructing the research to avoid obligations
  - The ethical question becomes about how research should be constructed
- Residual discomfort on the part of researchers
  - "I have this knowledge, I must do something with it ..."

Theoretical considerations

- What constrains the way that research is constructed and organized?
- What should be expected of researchers?

The Researcher/Subject Relationship

- What are the foundations that underpin the researcher/ subject relationship that give rise to obligations on the researcher?

Theoretical considerations

The Researcher/Subject Relationship

- It is important to avoid presuming a certain picture of research or of researchers
- Four potential models:
  i. clinician/patient
  ii. quasi-contractual
  iii. professional/client
  iv. person/person

Theoretical considerations

D. The Clinician/patient relationship

- Medical content
- Comparable risk of harms
- Many researchers are clinicians/clinical related

But:

- Clinicians are required to act for the benefit of patients
- Incidental findings in clinic?

Where does this get us?

What does this mean for researchers who are also clinicians?

- People (including researchers) are able to wear 'different hats'
  - Clinician on a train?
  - Boundaries of research – 'breaking cover'
- These boundaries will need to be examined in constructing the research
  - Researcher obligations: given by the research
  - Clinician obligations given through the clinic

Practical recommendations

5. Reaffirm the distinctiveness of research from treatment

- Principle of the respect for autonomy
- Transparency of process
- Separateness of researcher and subject
- Therapeutic misconception

"Here's how it all works and why this is different from treatment …"

Theoretical considerations

E. A Quasi-contractual relationship

- In the abstract, researchers do not have prior relationships with subjects
- Particular kinds of research dictate different kinds of relationships
- Part of the point of the consent process is to share and agree the nature of the relationship

But:

- We might think there is more to it than this

Theoretical considerations

F. Professional/client relationship

- Researchers make up a profession with a code of ethics which governs behaviour

But:

- What are grounds on which the relationship is based?
- Variation of researcher/subject relationship
- We can say something about the nature of research generally which may be of use here

Theoretical considerations

F. Professional/client relationship

Research as a social enterprise presumes:

- Some value in doing the research
- A genuine need for and contribution by participants
- Transparency of research processes
- Rigour of method

- But each of these are 'internal' to the agreement and to the research itself

Where does this get us?

The obligations of researchers to subjects should be governed by:

i. The details of the relationship are established in the consent process

ii. The constraints on this are imposed by the nature of the research enterprise

6. Practically, subject to these constraints, IFs might not be fed back for some research and this would form the basis of the 'consent agreement'

Theoretical considerations

G. Relationship between fellow persons

- How people ought to relate to each other
- Obligation to rescue
- Obligation to be helpful

But:

- Limited by convenience, ability, circumstance
- Circumstantial knowledge may make a difference
- E.g. fellow train passengers

Practical recommendations

7. Be clear about 'mandatory' feedback criteria

- Fellow persons/non-clinical obligation
- Duty to warn of foreseeable harm
  - Irrespective of subject's desire to know

Morally relevant criteria for deciding:

i. Severity (urgency)
ii. Treatability
iii. Certainly of diagnosis (possibility of a mistake)

Practical recommendations

7. Be clear about 'mandatory' feedback criteria

- Perhaps mitigated by informing the subject's clinician
- Based on the duty to warn

"Because of how I understand my duties, I will inform you (or your GP) in certain kinds of cases ..."

Conclusions

The Researcher/Subject Relationship

The obligations of researchers to subjects are determined according to the following:

(1) The details of the relationship are established in the consent process

(2) The limits on this are imposed by the nature of the research enterprise

(3) Background obligations of one person to another may come into play outside of this

Practical Recommendations

1. Be clear about the definition of an incidental finding
2. Ensure appropriate (participant-initiated) access to the in-study data/findings
3. Obtain appropriate consent, including a general discussion about feedback of incidental findings
4. Design the research to limit ethical problems with feedback of incidental findings
5. Reaffirm the distinctiveness of research from treatment
6. Expectations about feedback are established by the 'consent agreement'
7. Be clear about 'mandatory' feedback criteria

Practical Conclusions

Practical Decision Points:

- Research design, limiting IFs and feedback subject to research as a social enterprise
- How much to offer to feedback [and which will be the subject of choice by participants]
- Amount and practicality of access to in-study findings
- Determining mandatory feedback criteria