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Incidental Radiological Findings in the Research Setting and the Argument from Human Dignity

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Abstract

In research studies some collected data include Incidental Findings (IFs), i.e. findings "that potentially affect the health of a living being – if the diagnostic means were not intended to produce such findings".[1] They are found in up to 8% of brain MRI scans and as high as 41% in some CT scans; this wide difference in reported IFs is thought to be due in part to the wider field of view of CT scans which leads to better visualisation of additional organs.[2-4]

Given these facts, the ethical question arises: should the researcher tell the participant (or their healthcare provider) about an IF? After a brief evaluation of popular arguments put forward in the debate on how to handle IFs we'll recall what we owe human dignity and develop an argument from human dignity proving that disclosure of relevant IFs is without alternative.

Definitions

IFs differ in their severity; Hegenscheid et al. use a sliding scale where Category I IFs were normal or common in asymptomatic subjects (e.g. anatomical variants), Category II IFs were abnormalities needing further medical evaluation, and Category III IFs required immediate referral (e.g. acute brain infarction).[3-5] Similarly Lumbreras et al. classify IFs as minor, moderate and major but add correctly that depending on each individual an IF could be considered as major or minor and give the example of osteoarthritis as an age-related abnormality.[2] Katzman et al. reported that clinically serious IFs have a much lower prevalence of 1.1%; Illes et al. report that between 2 and 8% of findings have immediate clinical consequences. [6-11]

To Disclose or Not? A moral dilemma

Previously, it was uncontested in research ethics that, out of respect for their autonomy, there is a prima facie duty to inform a participant about any relevant IFs. According to this view, the decision not to disclose the finding can only be morally permitted for reasons that ostensibly outweigh the duty to disclose. Two reasons often put forward for not disclosing a finding are protection of the subject, and respect for personal autonomy. Non-disclosure could be required in order to protect the participant, e.g. from unnecessary psychological distress, [10] and respect for autonomy can be a reason for non-disclosure in the rare case that the right not to know was explicitly claimed by the participant with an acknowledgement of the consequences, and if there are no moral reasons to deny that right.

A duty to disclose IFs – limited only by conditions (a) and (b) – has, however, been questioned by several authors in recent years, mostly in relation to genetic research. [7-10] If there are convincing reasons for denying the duty to disclose IFs, one would also have to investigate whether they apply to IFs in radiological examinations carried out in non-interventional studies such as the UK Biobank or the Multi-Ethnic Study of Atherosclerosis (MESA) studies. [6] One argument for denying such a duty is that in a research context, no duty to inform exists because such a duty only rises from the patient-doctor relationship. [1] Another argument is that, in the case of genetic research, the relevant information mostly concerns risks of diseases and not manifest or actual diseases. Radiological IFs, though, often indicate manifest pathologies and not merely risks.

However, there is a serious moral case for non-disclosure. The moral duty not to harm research participants is contradicted by the moral duty not to produce false or useless research results by compromising a study's methodological integrity, as disclosing IFs compromises the integrity of the study, providing study subjects with information about their health that is not available to the general population which they are supposed to represent. [14] So the researcher is facing a moral dilemma: they must decide between two ethical demands that cannot both be met. What shall they do?

What Do We Owe Human Dignity?

It is thought that the duty of care is the most important moral principle protecting volunteers in medical research. [11-13] But does this go far enough in non-interventional research? [15] The researcher-participant contract – which can also be formally entered in the informed consent process – could state that the participant abstains from being informed about potential IFs. Given such a disclaimer, not informing the participant about IFs might be seen as legitimate. But is it? In order to examine this claim, we simply rely on three rather weak assumptions about the normative content of the concept of human dignity that can be supposed to be widely uncontroversial:

(I) “Human dignity” is a normative concept that, in the moral system of democratic constitutional states, designates a set of properties that human beings possess qua being human. It also legitimizes the expectation of a human being to be treated by others in a certain way.
(II) Someone’s human dignity has to be respected independently of potentially beneficial consequences for her. Insofar human dignity has stronger normative implications than the duty of care.
(III) If human dignity is attributed to someone, this person can expect not to be treated by others in a degrading way or as anything other than the potential source of ends and actions and not as a mere means to someone else’s end.

In order to assess the consequences of these assumptions for the handling of IFs, it is helpful to see what not informing a participant about an IF might look like in practice.

Non-disclosure in Practice

Let us assume that a participant – who has agreed not to be informed about potential IFs in a prior consultation with the researcher – asks after the examination whether “something was found”. How should the researcher react to this question? One thing is for clear: it is not morally permissible for them to avoid answering it, or to avoid meeting the participant after the examination. Such a form of not informing by refusing to talk to the participant might be justifiable by a paternalist account of the duty of care. But it is clearly disrespecting the human dignity of the participants. For in this case, the participant would be treated only as a means to the end of conducting a study, without being respected to the minimal degree that arises in direct interaction.

If refusing to communicate is not possible as a way of avoiding informing the participant, the researcher has two alternatives: contrary to the truth, they could (a) deny that “something was found”, or (b) refuse to inform the participant by referring to the fact that they agreed to forfeit their right to be informed in the informed consent process. The duty of care may allow for both options under certain circumstances. But in fact, both are problematic. Lying (a) is not a suitable form of non-disclosure, because it is a deliberate deception. Refusing to inform (b) can also hardly be considered as morally permissible. In this case, the participant who seeks to be informed could claim that they did not understand the whole extent of what they had agreed to in the consent process. Or they could say that they changed their mind about giving up their right to be informed. If an IF was discovered that is obviously clinically relevant, such as a life-threatening tumour that can be operated on, there is no doubt that it cannot be morally permissible for the researcher to insist on the principle “pacta sunt servanda” (according to which one is bound by entering into a contract forever) and to withhold the information about the IF from the participant, even though it would otherwise enable them to begin a potentially life-prolonging therapy. [11] Insisting on the contract would run counter to the common intuition that morality demands to release someone from a contractual obligation if this means that a life-threatening situation for that person can probably be solved or alleviated, and cancelling the contract is tolerable for the other party involved.

If we weigh up the choices, it is clear that the latter condition is also fulfilled in a case like this. Not disclosing the IF would prevent the participant from beginning potentially life-prolonging therapy as soon as possible. No comparable harm at all will come to the researcher by informing the participant.

The potential harm that might be done to third persons and future patients in particular, by disclosing the IF, is irrelevant. There are two reasons for this: first, in the informed consent process, the participant has – if we regard the researcher-participant relationship as a contract – only entered a contract with the researcher, and not also with third persons who might benefit from the research.

Second, participating in a study cannot establish a special moral duty of the participant – neither towards humanity, a certain community, or other individuals – that would exceed the moral duties that persons have independently of participating in the study. Hence burdening participants with special moral duties and thereby harming their physical integrity is incompatible with respecting their dignity. Therefore, no morally legitimate form of non-disclosure is available to the researcher. The only exception would be if the participant insisted on their right not to know.

Furthermore, human dignity also demands that we help someone in an emergency situation if helping is possible and reasonable for a third party. Therefore, even if there is no treatment contract between researcher and participant, the researcher has the duty to help the participant. This is the case even more so if the IF is sufficiently serious to call the situation of the participant an emergency and if the researcher is also a physician – which they usually are. [12] The latter means that they are capable of recognizing the emergency situation and of providing or arranging help.

Conclusion

Referring to human dignity enables us to see that in many cases disclosing IFs is morally required. That does not mean that a researcher is morally required to disclose all IFs as even a physician in a patient-doctor relationship is not required to do so, after all. Category I or minor IFs that have, according to current medical knowledge, no clinical significance might for example unnecessarily scare the participant. [2-5] It is these IFs and only them that might not be disclosed, but in order to take this paternalistic stance which censors the disclosure "in order to protect" the subject from stress, the research protocol would need very clear guidelines on which IFs would be disclosed. [13] However, respect for the human dignity of the participant requires taking seriously the fact that their life is self-determined. Relevant decisions that affect their life or the conduct of their life should not be subject to the researcher's discretion. Hence, Category II and III IFs could affect a subject's health status and therefore should be disclosed. Although management of IFs will vary between research canters there are guidelines in Europe which indicate that research participants should be informed of "relevant" IFs. [13-15] If "relevant" is understood to include all IFs that do not belong to Category I this is what is required in order to respect the participants' human dignity.

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