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EDITORIAL
Issues raised by "incidental findings" and their ethical implications

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Recent years have seen a boom in literature on the subject of the ethical problems posed by "incidental findings" (IFs).

"IFs have been defined as findings having potential health or reproductive importance for an individual, discovered in the course of conducting a particular study (in research, clinical care or screening) but beyond the aims of that study" [1].

Attention has focused particularly on IFs in the field of research [2].

Researchers often consider it best not to reveal the existence of potentially relevant IFs to participants. Among the reasons for this approach are: the desire not to impair the rigour of scientific procedures; the desire not to fuel so-called "therapeutic misconceptions" (the erroneous belief by participants that they will benefit from participating in a trial [3]); the considerable uncertainties that often surround IFs; the fact that the researcher/participant relationship is frequently of limited duration (and researchers are thus not involved in the subsequent follow-up or therapeutic procedures).

The development of new technologies and, above all, the possibility of acquiring and storing enormous quantities of information on an individual's complete genetic heritage easily, quickly and relatively cheaply, have nevertheless led to a re-examination of the issues at stake. Current thinking tends to favour an obligation to inform individuals of IFs that concern them, albeit within certain limits and bearing in mind the varying circumstances. There appears to be general agreement on two main criteria:

- firstly, clinically relevant IFs should be revealed in cases where either preventive or therapeutic treatment is available. In the case of IFs concerning pathologies for which no treatment is available, on the other hand, revelation would only lead to anxiety and should therefore be omitted;
- secondly, the existence of IFs should be revealed using due caution and bearing in mind all the circumstances. Information concerning minors and adults, for instance, should clearly be handled differently, and particular caution should be exercised when revealing genetic information that is of relevance not only for an individual but also for family members (IFs, for instance, that have potential reproductive importance). Another situation that calls for special attention is when IFs are unconfirmed. Highly dubious IFs may emerge in the early stages of research and generally involve areas unrelated to the original line of enquiry.

There may naturally be conflicting interpretations of these criteria: researchers, for instance, may not have the specific skills necessary to assess the clinical relevance or level of uncertainty of IFs.

The above criteria are nonetheless in line with the recommendations of respected organisations. For example, already in 2005 the Council of Europe, in Article 27 of *the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research*, recommended that: "If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counselling. In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of a participant not to receive such information" [4].

This is why many biobanks and genetic data archives already have policies in place for the handling of IFs and their return to the original contributors, as suggested by a respected working group funded by the National Institutes of Health [5].

Some facilities routinely screen samples for specific genes known to affect health before research procedures are initiated [6]. A similar protocol is generally followed in radiological imaging studies, where a radiologist usually examines the images before they are passed to researchers. However, implementation of these policies is not easy. The problems raised by the unprecedented increase in available genetic tests are well known, and it would not be easy to draw up a list of the genes for which screening should routinely be performed.

Even where guidelines have been established for the handling of IFs by researchers, a case-by-case assessment is always necessary. One obvious example is misattributed paternity, which may emerge in various clinical or research settings. This is usually cited as the typical case in which, while there may be no clinical relevance, those directly affected would probably not wish to be kept in the dark.

Another factor that makes it difficult to establish general criteria is the difference in procedures for ascertaining the wishes of those concerned – in other words, their consent or refusal to be informed of

possible IFs – prior to research. Some consent forms include numerous details, while others contain only a minimum. These problems are sometimes addressed through the use of a filter system, which allows the subject to declare in advance which type of IFs he or she wishes to know, to the exclusion of others.

The handling of IFs is thus far more complicated than the simpler problem of the "return of results" in the biomedical research field, and calls for specific policies. It also reveals the fineness of the lines between the research and clinical settings and between IFs and research results as such. IFs are often actual research results with clinical, diagnostic and preventive or therapeutic relevance.

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